CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ENDOVASCULAR TECHNOLOGIES, INC.

I. PREAMBLE

Endovascular Technologies, Inc. ("EVT") has been in the business of developing, marketing and selling the ANCURE Endograft System ("Ancure") for the treatment of abdominal aortic aneurysms ("AAA"). On June 12, 2003, EVT entered into a Settlement Agreement with the United States and this Corporate Integrity Agreement ("CIA") is incorporated by reference into the Settlement Agreement. On June 16, 2003, EVT announced that it was ceasing operations. EVT is currently a wholly owned subsidiary of Guidant Corporation ("Guidant"). EVT hereby enters into this CIA with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") and Guidant hereby enters into certain specified provisions of this CIA in order to promote compliance by its officers, directors, employees, contractors, and agents with the statutes, regulations, and written directives of Medicare, Medicaid, Food and Drug Administration ("FDA") compliance regulations and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) ("Federal health care program requirements"). The parties agree that certain obligations in this CIA shall apply only if EVT or Guidant re-enter the AAA repair market.

Guidant is the parent corporation of EVT. Since 1995, Guidant has operated a comprehensive, voluntary compliance program, which, as represented by Guidant, includes regular training to all Covered Persons, as defined in section II.C of this CIA, concerning Guidant's Code of Business Conduct, and related compliance programs to all appropriate employees. This training also includes review of disciplinary procedures aimed, in part, at ensuring that Guidant's activities are in compliance with all Federal health care program and FDA requirements and meeting Guidant's goals of continuing to promote high ethical standards in the conduct of Guidant's business practices. Guidant agrees to continue the operation of its compliance measures in accordance with the terms set forth below for the term of this CIA. Guidant may modify its voluntary compliance

measures as appropriate, but, at a minimum, Guidant will ensure that during the term of this CIA, it shall comply with certain integrity obligations enumerated in this CIA.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by EVT and Guidant under this CIA shall be 5 years from the effective date of this CIA ("Effective Date") (unless otherwise specified). The Effective Date shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) EVT and Guidant's final annual report; or (2) any additional materials submitted by EVT and Guidant pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be activities regulated by United States laws and regulations and shall be governed by the following definitions:

1. "Covered Persons" includes all officers, employees, contract workers, and agents of Guidant and EVT located in the United States.

2. "Relevant Covered Persons" includes those employees, contract workers or agents involved in aspects of marketing, sales or FDA reporting in compliance with the regulatory and statutory obligations related to medical device reporting and corrective and preventative actions located in the United States and as further defined in each relevant provision of this agreement.

3. "Compliance Officer" means an individual possessing suitable knowledge, training, education, and credentials in the medical device manufacturing process who will function exclusive of and in addition to the management representative as required by 21 C.F.R. § 820.20(b) for EVT.

4. "Compliance Committee" means a group of individuals from senior management, in accordance with section III.C.2, who will function

exclusive of and in addition to the management review pursuant to 21 C.F.R. § 820.20(c).

III. CORPORATE INTEGRITY OBLIGATIONS

EVT and Guidant shall maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* Guidant represents that it currently maintains the position of Chief Compliance Officer. Within 90 days after the Effective Date, EVT shall ensure it appoints an individual who meets the requirements of section II.C.3 of the CIA to serve as its Compliance Officer ("Compliance Officer") and to ensure that the requirements of 21 C.F.R. § 820.20 are met. The Chief Compliance Officer and Compliance Officer shall ensure that EVT and Guidant develop and implement policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with FDA and Federal health care program requirements. The Chief Compliance Officer and Compliance Officer shall be a member of senior management of their respective companies, shall make periodic (at least quarterly) reports regarding compliance matters directly to their respective Boards of Directors, and shall be authorized to report on such matters to their respective Boards of Directors at any time. The Chief Compliance Officer and Compliance Officer shall be responsible for monitoring the day-to-day compliance activities as well as for any reporting obligations created under this CIA.

EVT and Guidant shall report to OIG, in writing, any changes in the identity or position description of either the Chief Compliance Officer or Compliance Officer, or any actions or changes that would affect the Chief Compliance Officer or Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. *Compliance Committee.*

a. EVT shall establish a Compliance Committee within 90 days of the Effective Date. This committee shall be comprised of the President of EVT and the Compliance Officer and meet the requirements of section II.C.4. of this CIA. The Compliance

Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).EVT shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

b. Guidant shall establish management oversight groups in each business unit that will function as a compliance committee. Such a management oversight group shall satisfy the requirements of 21 CFR 820.20 and shall include members of senior management of the business unit necessary to meet the requirements of 21 CFR 820.20(c) (e.g. senior executives of relevant departments such as human resources, audit and operations).

B. Written Standards.

1. *Code of Business Conduct.* Guidant represents that it has established a written Code of Business Conduct. EVT has adopted that Code of Business Conduct. To the extent not already accomplished, EVT shall distribute the Code of Business Conduct to all Covered Persons of EVT within 90 days after the Effective Date. EVT shall make the promotion of, and adherence to, the Code of Business Conduct an element in evaluating the performance of all employees. The Code of Business Conduct shall, at a minimum, set forth:

a. EVT and Guidant's commitment to full compliance with all FDA and Federal health care program requirements;

b. EVT and Guidant's requirement that all of their Covered Persons shall be expected to comply with all Federal health care program requirements, FDA regulatory requirements and with Guidant's own Policies and Procedures as implemented pursuant to section III.B (including the requirements of this CIA);

c. the requirement that all of EVT and Guidant's Covered Persons shall be expected to report to their respective Compliance Officers or other appropriate individual designated by EVT or Guidant any suspected violations of Federal health care program requirements, FDA regulatory requirements or of EVT and Guidant's own Policies and Procedures;

d. the possible consequences to both EVT and Guidant's Covered Persons of the failure to comply with Federal health care program requirements, FDA regulatory requirements and with EVT and Guidant's own Policies and Procedures and the failure to report such noncompliance; and

e. the right of all individuals to use the Disclosure Program described in section III.E, and EVT and Guidant's commitment to maintain confidentiality, as appropriate, and nonretaliation with respect to such disclosures.

Unless already accomplished, within 90 days after the Effective Date, each of EVT's Covered Persons shall certify, in writing, that he or she has received, read, understood, and shall abide by Guidant's Code of Business Conduct. New Covered Persons shall receive the Code of Business Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

EVT and Guidant shall, at least annually, review the Code of Business Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Code of Business Conduct shall be distributed within 30 days after finalizing such changes. Each Covered Person shall certify that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of such revisions.

2. *Policies and Procedures.* To the extent not already accomplished, within 120 days after the Effective Date, EVT and Guidant shall implement written Policies and Procedures regarding the operation of EVT and Guidant's compliance program and their compliance with Federal health care program requirements and FDA regulatory requirements except as described below with respect to EVT. At a minimum, the Policies and Procedures shall address:

a. the subjects relating to the Code of Conduct identified in section III.B.1;

b. written Medical Device Reporting ("MDR") procedures to include those procedures required by 21 C.F.R. § 803.17;

c. written policies and procedures for employees on how to handle customer complaints and MDRs in accordance with 21 § C.F.R. 803;

d. criteria outlining the minimum qualifications for the specified position filled by a specific person (or persons) who, by reason of background, education, or experience, is (are) competent to maintain the MDR and complaint handling system in accordance with 21 C.F.R. § 803;

e. complaint handling procedures, including guidelines for evaluating and investigating complaints and implementing the appropriate corrective action to ensure that problems have been remedied and that recurrence of problems have been prevented in accordance with 21 C.F.R. § 820.198;

f. corrective and preventive action procedures to analyze quality problems, and investigate the root cause of nonconformities reported in accordance with 21 C.F.R. § 820;

g. procedures to ensure that corrective action is effective using appropriate statistical methods and does not adversely affect the finished product in accordance with 21 C.F.R. § 820;

h. procedures in place to notify appropriate individuals directly responsible of quality problems and their correction in accordance with 21 C.F.R. §820;

i. recall and notification procedures to promptly notify FDA, hospitals, and affected physicians of any correction or removal of a device in accordance with the reporting requirements of FDA's corrections and removal regulations in 21 C.F.R. Part 806;

j. Proper circumstances to report to the FDA device modifications that affect the safety or effectiveness of the device in accordance with 21 C.F.R. § 814;

k. the proper procedures and processes for modification of the device's Instructions for Use in accordance with 21 C.F.R. § 814;

l. pre-market application approval procedures in accordance with 21 C.F.R. § 814;

m. device modification procedures in accordance with 21 C.F.R. § 814; and

n. establishing and maintaining MDR, Removals and Corrections, and Quality Systems files in compliance with 21 C.F.R. §§ 803.18, 806.20 and 820.198.

Within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

Given the discontinuation of EVT's operations, EVT shall be required to have in place those only policies and procedures set forth in Section III B. 2. a, b, c, d, e, i, and n. In the event that EVT commences the sale or distribution in interstate commerce of any AAA device during the term of this agreement, EVT shall have in place all of the policies and procedures set forth in Section III B. 2 prior to any such sale or distribution.

At least annually (and more frequently, if appropriate), Guidant shall assess and update as necessary the Policies and Procedures described above. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 120 days after the Effective Date, EVT shall provide at least two hours of general training to each of EVT's Covered Persons. This training, at a minimum, shall explain EVT's:

a. CIA requirements; and

b. EVT's Compliance Program (including the Code of Business Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the general training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. EVT shall administer an assessment tool to Covered Persons subject to general training, which passage of this exam or assessment tool reflects an understanding of the requirements outlined in section III.C.1 of this CIA. After receiving the initial training described above, each of EVT's Covered Persons shall receive at least one hour of general training annually.

2. *Specific Training.*

a. *Adverse Event Reporting Training Module.* Unless otherwise performed within six months prior to the Effective Date, within 120 days after the Effective Date, each sales representative, marketing professional and customer or technical service representative world wide shall receive at least one hour of adverse event reporting training. This training shall include:

(1) training in the policies and procedures applicable to the reporting of adverse events.

(2) The legal sanctions for improper adverse event reporting

b. *Complaint Handling and MDR Training Module.* Unless otherwise performed within six months prior to the Effective

Date, within 120 days after the Effective Date, each Relevant Covered Person responsible for deciding what adverse events to report as MDRs shall receive at least 3 hours of Complaint Handling and MDR training. This specific training shall include a discussion of:

(1) training in the regulations and policies regarding receipt, investigation and evaluation of customer complaints and MDRs;

(2) policies, procedures, and other requirements applicable to the documentation of complaints and MDRs;

(3) the personal obligation of any individual involved in the complaint handling and MDR submission process to ensure that material is complete, accurate and in compliance with any and all applicable complaint handling and MDR regulations;

(4) the legal sanctions for improper complaint handling and MDR reporting; and

(5) examples of proper MDR reporting practices.

c. *Corrective and Preventative Action Training Module.* Unless otherwise performed within six months prior to the Effective Date, within 120 days after the Effective Date, each Relevant Covered Person responsible for the corrective and preventive action program shall receive at least 4 hours of Corrective and Preventative Action training. This specific training shall include a discussion of:

(1). training in the regulations and policies regarding the implementation of corrective and preventative actions;

(2). policies, procedures, and other requirements applicable to the documentation of corrective and preventative action;

(3). the personal obligation of any individual involved in the corrective and preventative action process to ensure that

material is complete, accurate and in compliance with all applicable complaint handling and MDR regulations;

(4). the legal sanctions for the failure to implement corrective and preventative actions; and

(5). examples of proper corrective and preventative action procedures.

Any person providing training shall be knowledgeable and experienced in the subject area.

Unless otherwise performed within six months prior to the Effective Date, Relevant Covered Persons shall receive the applicable training set forth above within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later. An EVT or Guidant employee who has completed the specific training shall review a new Relevant Covered Person's work, to the extent that the work relates to corrective and preventative action procedures or MDR reporting requirements, until such time as the new Relevant Covered Person completes his or her applicable training and can demonstrate a thorough understanding of the requirements. EVT and Guidant shall administer an assessment tool to Relevant Covered Persons in which passage of the assessment tool reflects an understanding of the requirements outlined in section III.C.2 of this CIA.

After receiving the initial specific training described above, each Relevant Covered Person shall receive at least 3 hours of this specific training annually. Guidant and EVT shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program and FDA requirements, any issues discovered during internal or external audits, and any other relevant information.

Guidant and EVT may provide the training required under this CIA through appropriate computer-based training approaches. In that event, all applicable references to "hours" in this section III.C shall mean "normative hours" as that term is used in the computer-based training industry. If Guidant or EVT chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the Covered Persons or Relevant Covered Persons who are receiving such training.

3. *Certification.* Each individual who is required to complete such training shall certify, in writing, or in electronic form that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

D. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 120 days after the Effective Date, EVT shall retain at least one entity, such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to assess and evaluate EVT's program for compliance with MDR reporting requirements in accordance with 21 CFR 803 ("MDR Review"). In performing such review, the IRO shall review, address and analyze EVT's policies and procedures related to MDR reporting practices to ensure proper reporting in compliance with FDA reporting regulations. In the event that EVT commences the sale or distribution into interstate commerce of any AAA device during the term of this CIA, then EVT shall retain an IRO to perform Quality System Reviews to assist EVT in assessing and evaluating its entire quality program for compliance with applicable FDA quality and reporting regulations for device manufacturers which include, but are not limited to,

1) an examination of corrective and preventative action procedures;

2) the process for reporting to the FDA device modifications;

3) pre-market approval procedures;

4) any instructions for use clarifications, and certain other obligations pursuant to this CIA and the Settlement Agreement.

Each IRO retained by EVT shall have expertise in the subject matter of the IRO's review. The OIG must approve EVT's selection of each IRO prior to its engagement. Each IRO shall assess, along with EVT, whether it can perform the IRO review in a professionally independent and/or objective fashion, as appropriate to the nature of

the engagement, taking into account any other business relationships or engagements that may exist.

To the extent the scope of EVT's operations and corresponding FDA regulatory requirements change, the scope of the IRO's engagement may be altered to correspond with EVT's operational activities and regulatory requirements. EVT must notify the OIG in writing within 30 days of the aforementioned changes, and the OIG must provide written approval of any changes in the IRO's engagement.

b. Retention of a Data Monitoring Committee. If EVT or any other Guidant subsidiary continues to manufacture the Ancure® device or any next generation abdominal aortic aneurysm device, within 90 days after the Effective Date, EVT or the appropriate Guidant entity shall retain a Data Monitoring Committee ("DMC"). The DMC shall be composed of, at a minimum, two physicians and a statistician. One physician shall be an interventional cardiologist ("IC") and have knowledge and clinical experience related to the abdominal aortic aneurysms. The other physician shall be a cardiologist or a physician with a specialty that understands the disease process related to abdominal aortic aneurysms. The DMC shall be independent of EVT or the appropriate Guidant entity.

c. Frequency of Quality Systems Review. If applicable, the Quality Systems Review shall be performed for the first Reporting period, and, thereafter, a review shall be conducted for any Reporting Period in which changes occur as a result of changes in laws, regulations, or internal or external policies, procedures and systems. The IRO shall perform all components of each annual Quality Systems Review.

d. Frequency of MDR Review. The IRO shall perform the MDR Review for each Reporting Period. In the event that EVT and/or Guidant no longer has MDR reporting requirements related to the Ancure® device or any next generation abdominal aortic aneurysm ("AAA") device, EVT and/or Guidant shall sign a certification under the penalty of perjury, that it no longer is subject to the FDA's MDR reporting requirements. After OIG receives this certification, OIG

will notify EVT and Guidant in writing that it has satisfied section III.D.5 of the CIA.

e. Frequency of DMC Review. If applicable, the DMC shall conduct quarterly reviews during the first two Reporting Periods and then semi-annual reviews thereafter.

f. Retention of Records. The IRO and EVT shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and EVT) related to the reviews.

2. Quality Systems Review. If applicable, within 120 of re-entry into the market for AAA repair devices, the IRO shall review EVT's handling of nonconforming product, complaint handling process, the method for reporting to the FDA changes in the device, and any instructions for use ("IFU") clarifications if applicable. The Quality Systems Review shall also review and analyze (i) EVT's adherence to Management Responsibility and Design Controls; and (ii) EVT's implementation of Policies and Procedures related to MDR reporting practices in compliance with 21 C.F.R. § 803 and corrective and preventative action procedures in compliance with 21 C.F.R. § 820.100. The IRO shall also randomly select and review a sample of 20 MDRs submitted by or on behalf of EVT to FDA. The MDR complaints shall be analyzed in accordance with regulations and guidance to verify these events were reportable in accordance with 21 C.F.R. § 803.

3. Quality Systems Review Report. If applicable, within 30 days after the completion of the Quality Systems Review pursuant to Section III D 2, the IRO shall prepare a report based upon the Quality Systems Review performed ("Quality Systems Review Report"). The Quality Systems Review Report shall include the IRO's findings and supporting rationale regarding:

a. a description of EVT's procedures for handling nonconforming product, implementing corrective and preventative actions, complaint handling , and reporting to the FDA changes in the device, including changes to the instructions for use. The report shall also determine EVT's adherence to Management Responsibility and Design Controls and EVT's Policies and Procedures related to MDR reporting practices in compliance with 21 C.F.R. § 803 and

corrective and preventative action procedures in compliance with 21 C.F.R. § 820.100.

b. the extent to which EVT's policies and procedures related, at a minimum, to, control of nonconforming product, corrective and preventative action, complaint handling, device modification and IFU procedures, EVT's adherence to Management Responsibility and Design Controls and MDR reporting systems are in compliance with FDA's regulations; and

c. the IRO's recommendations on improving the corrective and preventative action, complaint handling, device modification and IFU procedures and MDR policies and procedures.

4. *MDR Review.* The MDR Review shall include a sample of complaints that were not reported as MDRs. The IRO shall randomly select and review a statistically significant sample of such complaints in the EVT complaint handling database or other similar mechanism used to track complaints. The sample shall be reviewed based on the supporting documentation available at EVT or under EVT's control in accordance with applicable regulations. The sample shall be analyzed and results shall be determined based on FDA regulations and guidance used to determine whether the events were MDR reportable. EVT shall report any Errors (as defined in Appendix A) in the MDR Review in accordance with section III.H of this CIA. The applicable definitions, procedures, and reporting requirements are outlined in Appendix A to this CIA, which is incorporated by reference.

5. MDR Review Report. The IRO shall prepare a report based upon the MDR Review performed. This report shall evaluate whether EVT's policies and procedures related to complaint handling and MDR reporting systems are in compliance with FDA's regulations, and include the IRO's recommendations on improving the complaint handling and MDR policies and procedures. In addition, information to be included in the MDR Review Report related to the non-reportable complaints is detailed in Appendix A.

6. *DMC Review.* If applicable, the DMC shall review complaints, MDRs, conduct failure investigations, conduct trend and root cause analysis, analyze corrective and preventative actions and assess the clinical adequacy of the current device design and any device modifications.

7. *DMC Report.* If applicable, the DMC shall provide to the OIG a written report that encompasses the following from its review: (a) summary of the DMC's minutes; (b) the type, frequency and nature of the complaints related to the device; (c) summaries of failure investigations; (d) any trend or statistical analysis; and (e) any root cause analysis.

8. Validation Review. In the event OIG has reason to believe that: (a) the Quality Systems Review, MDR Review or DMC Review fails to conform to the requirements of this CIA; or (b) the IRO's findings, MDR Review or DMC Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Quality Systems Review, DMC Review or the MDR Review complied with the requirements of the CIA and/or the findings, MDR Review or DMC Review results are inaccurate ("Validation Review"). EVT shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents so long as it is initiated within one year after EVT's final submission (as described in section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify EVT and Guidant of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Guidant or EVT may request a meeting with OIG to discuss the results of any Quality Systems Review, DMC Review or MDR Review submissions or findings; present any additional or relevant information to clarify the results of the Quality Systems Review or DMC Review or to correct the inaccuracy of the MDR Review; or propose alternatives to the proposed Validation Review. Guidant and EVT shall provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Quality Systems Review, MDR Review or DMC Review with Guidant and EVT prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

9. *Independence/Objectivity Certification.* The IRO shall include in its report to EVT and Guidant a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the engagement, with regard to the Quality Systems Review or MDR Review and that it has concluded that it is, in fact, independent and/or objective.

10. *Response to IRO and DMC Reports:* Within 60 days of the delivery of the IRO or DMC Reports referred to in subparagraphs 1 through 9 above, EVT and Guidant shall have the right to submit a written response to the findings of the IRO or the DMC to OIG.

E. Disclosure Program.

EVT and Guidant shall maintain their Disclosure Program, which includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with EVT and Guidant's policies, conduct, practices, or procedures with respect to a Federal health care program, believed by the individual to be a potential violation of criminal, civil, or administrative law. EVT and Guidant shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, EVT or Guidant shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be available to OIG, upon request.

F. Ineligible Persons.

1. *Definition*. For purposes of this CIA, an "Ineligible Person" shall be an individual or entity who: (a) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or (b) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

2. *Screening Requirements*. Within 120 days after the Effective Date, EVT and Guidant shall ensure that all Covered Persons of EVT and Guidant whose job responsibilities relate to: (1) sales , marketing and regulatory reporting activities for Government Reimbursed Products; or (2) the negotiation, implementation, and any reporting of information related to, government contracts are not Ineligible Persons. To ensure that such persons are not Ineligible Persons, EVT and Guidant shall screen such persons prior to engaging their services by: (a) requiring such persons to disclose whether they are Ineligible Persons; and (b) appropriately querying the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov) (these lists shall hereinafter be referred to as the "Exclusion Lists"). Thereafter, EVT and Guidant shall review its list of such persons against the Exclusion Lists annually. In addition, EVT and Guidant shall require such persons to disclose immediately any debarment, exclusion, suspension, or other event that makes such person an Ineligible Person.

If EVT or Guidant has actual notice that such person has become an Ineligible Person, Guidant or EVT shall remove such person from responsibility for, or involvement with, Guidant's business operations related to the Federal health care programs and shall remove such person from any position for which the person's compensation or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

3. *Pending Charges and Proposed Exclusions*. If EVT or Guidant has actual notice that a person identified in section F.2 is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment, involvement, or contract term, EVT or Guidant shall take all appropriate

actions to ensure that the responsibilities of that person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery by senior management of EVT or Guidant, EVT or Guidant shall notify OIG, in writing, of any ongoing investigation known to EVT or Guidant or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that EVT or Guidant has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. EVT or Guidant shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any. In addition, within 15 days after notification, EVT or Guidant shall notify OIG, in writing, of any adverse final determination made by a Federal, State, or local Government agency or accrediting or certifying agency regarding quality of care issues.

H. Reporting.

1. *Reportable Events.*

a. Definition of Reportable Event. For purposes of this CIA, a "Reportable Event" means anything brought to the attention of senior management at Guidant's corporate headquarters, that involves:

(1) a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws for which penalties or exclusion from any Federal health care program may be authorized;

(2) an adverse event or complaint occurred that Guidant and/or EVT was required to report as an MDR and Guidant and/or EVT failed to report to the FDA this adverse event or complaint as required pursuant to 21 U.S.C. § 360i, within 30 days.

A Reportable Event may be the result of an isolated event or a series of occurrences.

b. Reporting of Reportable Events. If senior management of EVT or Guidant determines through any means that there is a Reportable Event, EVT or Guidant shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

(1) a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and the FDA and Federal health care program authorities implicated;

(2) a description of EVT or Guidant's actions taken to correct the Reportable Event; and

(3) any further steps EVT or Guidant plans to take to address the Reportable Event and prevent it from recurring.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, EVT changes locations or sells, closes, purchases, or establishes a new business unit or location related to the furnishing of items or services that may be regulated by the FDA or reimbursed by Federal health care programs, EVT shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare provider number (if any), establishment registration number (21 C.F.R. § 807), and the corresponding contractor's name and address that has issued each Medicare provider number. All Covered Persons at each such business unit or location shall be subject to the applicable requirements in this CIA (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, EVT and Guidant shall submit a written report to OIG summarizing the status of their

implementation of the requirements of this CIA. This Implementation Report shall include:

1. the name, address, phone number, and position description of the Compliance Officer required by section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

2. if applicable, the names and positions of the members of the Compliance Committee required by section III.A;

3. a copy of the applicable Code of Business Conduct required by section III.B.1;

4. a copy of all Policies and Procedures required by section III.B.2;

5. a copy of all training materials used for the training required by section III.C, a description of such training, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

6. a certification by the Compliance Officer that:

a. the Policies and Procedures required by section III.B have been developed, are being implemented, and have been made available to all appropriate Covered Persons;

b. all Covered Persons have completed the Code of Business Conduct certification required by section III.B.1; and

c. all Covered Persons of EVT and applicable Relevant Covered Persons have completed the applicable training and executed the certification(s) required by section III.C.

The documentation supporting this certification shall be available to OIG, upon request. In the event that the Compliance Officer cannot certify to these items in their entirety, 30 days prior to submitting the Implementation Report, the Compliance Officer shall provide an explanation of any

deficiencies and a timetable for when the deficiencies will be remedied. This timetable must be approved by the OIG.

7. a description of the Disclosure Program required by section III.E;

8. the identity of the IRO(s), a summary/description of all engagements between EVT and the IRO, including, but not limited to, any outside financial audits or reimbursement consulting, and the proposed start and completion dates of the Quality Systems Review or MDR Review;

9. a certification from the IRO(s) regarding its professional independence and/or objectivity with respect to EVT;

10. a summary of personnel actions (other than hiring) taken pursuant to section III.F;

11. a list of all of EVT's locations (including locations and mailing addresses), the establishment registration number, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers;

12. a description of EVT and Guidant's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

13. the certification required by section V.C.

B. Annual Reports. EVT and Guidant shall submit to OIG Annual Reports with respect to the status of, and findings regarding, EVT and Guidant's compliance activities for each of the five Reporting Periods.

Each Annual Report shall include:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in section III.A;

2. a certification by the Compliance Officer that:

a. all Covered Persons have completed any Code of Business Conduct certifications required by section III.B.1;

b. all Covered Persons of EVT and applicable Relevant Covered Persons have completed the applicable training and executed the certification(s) required by section III.C;

The documentation supporting this certification shall be available to OIG, upon request.

3. a summary of any significant changes or amendments to the Policies and Procedures required by section III.B and the reasons for such changes and copies of any compliance-related Policies and Procedures that have been changed or amended during the Reporting Period;

4. a copy of all training materials used for the training required by section III.C (to the extent it has not already been provided as part of the Implementation Report), a description of such training conducted during the Reporting Period, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

5. if applicable, a complete copy of all reports prepared pursuant to the IRO's Quality Systems Review, MDR Review and, if applicable, the DMC's reports including a copy of the methodology used, along with a copy of the IRO's engagement letter;

6. EVT or the appropriate Guidant entity's response and corrective action plans related to any issues raised by the IRO or the Data Monitoring Committee;

7. a revised summary/description of all engagements between EVT and the IRO(s), including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, if different from what was submitted as part of the Implementation Report;

8. a certification from the IRO(s) regarding their professional independence and/or objectivity with respect to EVT and Guidant;

9. a summary of Reportable Events (as defined in section III.H) identified during the Reporting Period and the status of any corrective and preventative actions relating to all such Reportable Events;

10. a summary of the disclosures in the disclosure log required by section III.E that relate to: (a) manufacturing quality and labeling; (b) quality process; (c) engineering change controls; (d) complaint follow-up; (e) MDR reporting requirements or (f) pre-production design problems

11. a description of any personnel actions (other than hiring) taken by EVT or Guidant as a result of the obligations in section III.F, and the name, title, and responsibilities of any person who is determined to be an Ineligible Person under section III.F, and the actions taken in response to the obligations set forth in that Section;

12. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding; and

13. a description of all changes to the most recently provided list (as updated) of EVT's locations (including addresses) as required by section V.A.11, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, and the certification required by section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that: (1) to the best of his or her knowledge, except as otherwise described in the applicable report, EVT and Guidant are in compliance with all of the requirements of this CIA; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful.

D. Designation of Information. EVT and Guidant shall clearly identify any portions of their submissions that they believe are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt

from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. EVT and Guidant shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, D.C. 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

EVT and Guidant:

Kathleen Lundberg
Senior Vice President
Compliance Officer
4100 Hamline Avenue North
St. Paul, MN 55112
Telephone: 651.582.5454
Facsimile: 651.582.2385

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, and to the extent such items are not protected under appropriately asserted legal

privileges, OIG or its duly authorized representative(s) may examine or request copies of EVT and Guidant's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of EVT and Guidant's locations for the purpose of verifying and evaluating: (a) EVT and Guidant's compliance with the terms of this CIA; and (b) EVT and Guidant's compliance with the requirements of the FDA regulations and Federal health care programs in which it participates. The documentation described above shall be made available by EVT and Guidant to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Notwithstanding that fact, the existence of any such privilege shall not be used by EVT and Guidant to avoid its obligations to comply with the provisions of this CIA. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of EVT and Guidant's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. EVT and Guidant shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. EVT and Guidant's employees may elect to be interviewed with or without a representative of Guidant present. EVT and Guidant's employees, contractors, and agents shall have the right to be represented by counsel and any such employee, contractor, or agent may, at his or her option, be accompanied by counsel for EVT or Guidant and/or their personal counsel at any interview by the OIG. Notwithstanding such arrangement, the OIG recognizes that individuals have the right to refuse to submit to interviews, and EVT and Guidant shall not be obligated to require such individuals to submit to interviews. If any individual decides not to submit to an interview, such refusal shall not constitute a breach of this CIA.

VIII. DOCUMENT AND RECORD RETENTION

EVT and Guidant shall maintain for inspection all documents and records relating to FDA record keeping requirements, or to compliance with this CIA, for 6 years (or longer if otherwise required by law).

IX. DISCLOSURES

Consistent with HHS' FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify EVT and Guidant prior to any release by OIG of information submitted by EVT and Guidant pursuant to their obligations under this CIA and identified upon submission by EVT and Guidant as trade secrets, or information that

is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, EVT and Guidant shall have the rights set forth at 45 C.F.R. § 5.65(d). OIG shall follow all applicable laws concerning privacy and confidentiality, including the Federal Privacy Act, 5 U.S.C. § 553a, to the greatest extent allowed by law. The OIG shall provide the predisclosure notice required pursuant to 45 C.F.R. § 5.65(d) to the Compliance Officer at the address provided in section VI. Nothing in this CIA or any communication or report made pursuant to this CIA shall constitute or be construed as a waiver by EVT and Guidant of their attorney-client, work product, or other applicable privileges.

X. BREACH AND DEFAULT PROVISIONS

EVT and Guidant are expected to fully and timely comply with all of its CIA obligations. A breach of this CIA does not constitute a breach of the Settlement Agreement or Plea Agreement between EVT and the United States executed contemporaneously herewith. Any breach of the terms of those agreements does not constitute a breach of this CIA. Section X specifies all of the remedies available to the OIG if EVT and/or Guidant fail to satisfy its obligations under this CIA.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, EVT, Guidant and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day EVT or Guidant fails to have implemented any of the obligations described in section III:

a. a Compliance Officer;

b. a Compliance Committee;

c. a written Code of Conduct;

d. written Policies and Procedures;

e. training programs; and

f. a Disclosure Program.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day EVT fails to retain an IRO and DMC as required in section III.D.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day EVT or Guidant fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

4. A Stipulated Penalty of $2,000 (which shall begin to accrue on the date the failure to comply began) for each day EVT or Guidant employs or contracts with an Ineligible Person and that person: (a) has responsibility for, or involvement with, EVT and Guidant's business operations related to the Federal health care programs; or (b) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this Subsection shall not be demanded for any time period during which EVT and Guidant can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person).

5. A Stipulated Penalty of $1,500 for each day EVT or Guidant fails to grant access to the information or documentation as required in section VII. (This Stipulated Penalty shall begin to accrue on the date EVT or Guidant fails to grant access.)

6. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of EVT or Guidant as part of their Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG) or otherwise required by this CIA.

7. A Stipulated Penalty of $12,000 for each non-reported adverse event or complaint that the IRO determines should have been filed with the FDA as an MDR in accordance with FDA's reporting requirements. This Stipulated Penalty will apply if the IRO finds a 2% error rate or greater in the MDR Review pursuant to section III.D. of this CIA.

8. A Stipulated Penalty of $1,000 for each day EVT or Guidant fails to comply fully and adequately with any obligation of this CIA. In its notice to EVT or Guidant, OIG shall state the specific grounds for its determination that EVT or Guidant has failed to comply fully and adequately with the CIA obligation(s) at issue and steps EVT or Guidant shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after EVT or Guidant receives notice from OIG of the failure to comply.) A Stipulated Penalty as described in this subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under subsections 1-7 of this Section.

B. Timely Written Requests for Extensions. EVT or Guidant may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after EVT or Guidant fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after EVT or Guidant receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed. C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that EVT or Guidant has failed to comply with any of the obligations described in section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify EVT or Guidant of: (a) EVT or Guidant's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter"). Such demand letter shall specifically state the conduct that the OIG contends constitutes the basis for imposing the Stipulated Penalty.

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, EVT or Guidant shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance,

pursuant to the agreed upon provisions set forth below in section X.E. In the event EVT or Guidant elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until EVT or Guidant cures, to OIG's satisfaction, the alleged breach in dispute or an ALJ rules in EVT's or Guidant's favor. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in section VI.

4. *Independence from Material Breach Determination.* Except as set forth in section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that EVT or Guidant has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

a. a failure to report a Reportable Event related to EVT and take corrective action as required in section III.H;
b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in section X.A;

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section X.C; or

d. a failure to retain and use an IRO or, if applicable, a DMC in accordance with section III.D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA constitutes an independent basis for exclusion from participation in the Federal health care programs. Upon a determination by OIG that EVT or Guidant has materially breached its respective obligations under the CIA and that exclusion is the appropriate remedy, OIG shall notify EVT or Guidant, as applicable, of:

(a) EVT or Guidant's respective material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* EVT or Guidant shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. EVT or Guidant is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) EVT or Guidant has begun to take action to cure the material breach; (ii) EVT or Guidant is pursuing such action with due diligence; and (iii) EVT or Guidant has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, EVT or Guidant fails to satisfy the requirements of section X.D.3, OIG may exclude EVT or Guidant from participation in the Federal health care programs. OIG shall notify Guidant in writing of its determination to exclude Guidant (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Guidant may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to EVT or Guidant of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, EVT and Guidant shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought

pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether EVT or Guidant was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. EVT or Guidant shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders EVT or Guidant to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless EVT or Guidant requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

a. whether EVT or Guidant was in material breach of this CIA;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) EVT or Guidant had begun to take action to cure the material breach within that period; (ii) EVT or Guidant has pursued and is pursuing such action with due diligence; and (iii) EVT or Guidant provided to OIG within that period a

reasonable timetable for curing the material breach and Guidant has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for EVT or Guidant, only after a DAB decision in favor of OIG. EVT or Guidant's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude EVT or Guidant upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that EVT or Guidant may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. EVT or Guidant shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Guidant, Guidant shall be reinstated effective on the date of the original exclusion.

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, Guidant and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of EVT and Guidant;

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;

D. The undersigned EVT and Guidant signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF EVT AND GUIDANT

Kathleen Lundberg
Senior Vice President and
Chief Compliance Officer
Guidant Corporation

DATE June 30, 2003

Peter S. Spivack, Esq.
Hogan & Hartson, LLP
Counsel for
Endovascular Technologies, Inc. and
Guidant Corporation

DATE

ON BEHALF OF EVT AND GUIDANT

Kathleen Lundberg
Senior Vice President and
Chief Compliance Officer
Guidant Corporation

DATE

Peter S. Spivack, Esq.
Hogan & Hartson, LLP
Counsel for
Endovascular Technologies, Inc. and
Guidant Corporation

June 30, 2003
DATE

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Larry J. Goldberg

LARRY J. GOLDBERG
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

June 30 2003
DATE

APPENDIX A

A. MDR Review.

1. **Definitions**. For the purposes of the MDR Review, the following definitions shall be used:

a. Population: All adverse events or complaints in the complaint handling system related to abdominal aortic aneurysm devices that were not submitted to FDA as an MDR.

b. Sampling Unit. An adverse event or complaint related to abdominal aortic aneurysm devices that are captured in EVT's complaint handling system.

c. Error: Any adverse event or complaint in EVT's complaint handling system related to abdominal aortic aneurysm devices that were not reported to FDA, but should have been reported to the FDA under the FDA's MDR reporting requirements.

B. MDR Review Report.

The following information shall be included in the MDR Review Report.

1. **MDR Review Methodology.**

a. Review Objective. A clear statement of the objective intended to be achieved by the MDR Review.

b. Review Population. A description of the Population subject to the MDR Review and number of sampling units in the Population.

c. Sampling Unit. A description of the sampling unit used to perform this review.

d. Source of Data: A detailed description of all documentation relied upon by the IRO when performing the MDR Review.

e. Review Protocol: A narrative description of how the MDR Review was

conducted and what was evaluated.

2. MDR Review Results.

a. Provide number of sampling units examined.

b. Provide number of sampling units that were not reported as MDRs but should have been reported to the FDA under the FDA's MDR reporting requirements.

c. Provide a spreadsheet containing: a brief narrative description of each sampling unit (e.g., reason why it was included in EVT's complaint handling database or system) and reason why, including reference to the regulations (if applicable), it should or should not have been reported as an MDR.