DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CDRH Medical Device Reporting
P.O. Box 3002
Rockville, MD 20847-3002

FORM APPROVED: OMB No. 0910-0437
EXPIRES: 04/30/2006

FOR FDA USE ONLY

MEDICAL DEVICE REPORTING
BASELINE REPORT

PART 1

INSTRUCTIONS

Part 1 is a cover sheet for single or multiple copies of Part 2. The FDA Registration Number, (item 2.b.) and the Date of Baseline Report, (item 7.) must be provided on each attached Part 2. Return this form to the address listed above.

1. **TYPE OF BASELINE REPORT**

☐ Initial ☐ Annual Update

2. **FIRM INFORMATION** *(Reporting Site)*	3. **MANUFACTURER CONTACT INFORMATION**
a. Firm Name	a. Name
b. FDA Registration Number *(Reporting Site)*	b. Title
c. Street Address	c. Street Address
d. City	d. City
e. State / f. ZIP Code	e. State / f. ZIP Code
g. Country/Postal code *(if not U.S.)*	g. Telephone Number *(Include area code and extension)* ( )

4. NUMBER OF "Baseline Reports - Part 2" attached

5. ARE YOU THE U.S. AGENT FOR A FOREIGN MANUFACTURER PER 21 CFR 803, 807?

☐ Yes ☐ No

6. SIGNATURE

7. DATE

M M / D D / Y Y Y Y

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
Office of Surveillance and Biometrics
Division of Surveillance Systems, RSMB, HFZ-533
1350 Piccard Drive
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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MEDICAL DEVICE REPORTING - BASELINE REPORT

☐ INITIAL ☐ ANNUAL UPDATE

PART 2

INSTRUCTIONS: Complete ONE copy of the following information for EACH device model. If model is not used, select another identifier from the device's labeling. Refer to baseline instructions, separate from this form, for detailed guidance.

FDA REGISTRATION NUMBER

DATE OF BASELINE __ __ / __ __ / __ __ __ __ (M M / D D / Y Y Y Y)

1. **MANUFACTURING SITE(S) FOR THIS DEVICE**

a. **FDA Registration Number** ***(Manufacturing Site)***	b. **Firm Name** ***(Manufacturing Site)***

Note: *If more space is required attach additional Part 2 pages, providing items 1.a. & 1.b. Include the FDA reporting site registration number* ***(Part 1, item 2.b.),*** *the date* ***(Part 1, item 7.),*** *device brand name* ***(Part 2, item 2.)****, and model* ***(Part 2, item 4.)*** *for a cross reference on each page.*

2. DEVICE BRAND NAME

3. DEVICE GENERIC NAME

4. DEVICE MODEL NUMBER

5. DEVICE CATALOG NUMBER

6. OTHER DEVICE IDENTIFIER

7. FDA PRODUCT CODE *(Refer to FDA Classification Names booklet.)*

8. MANUFACTURER'S DEVICE FAMILY NAME

9. RELATED DEVICE IDENTIFICATION *If this device, or a substantially similar device, was previously distributed with a different device identification, provide the following:*

a. Previous Device Identifier

b. Type of Identifier
☐ Model
☐ Catalog
☐ Other

c. Date of Prior Baseline Report __ __ / __ __ / __ __ __ __ (M M / D D / Y Y Y Y)

10. BASIS FOR MARKETING
a. 510 (k) _____ ☐ Yes, Number _____ ☐ No
b. PMA _____ ☐ Yes, Number _____ ☐ No
c. Preamendment ___ ☐ Yes ☐ No
d. Transitional _____ ☐ Yes ☐ No
e. 510 (k) Exempt ___ ☐ Yes ☐ No

11. DEVICE LIFE
a. Shelf Life _____ months ☐ N/A
Is shelf life labeled? *(Go to 11.b. if N/A)* ☐ Yes ☐ No
b. Expected Life _____ months ☐ N/A ☐ Not Established/Indefinite

12. DATE DEVICE FIRST MARKETED __ __ / __ __ / __ __ __ __ (M M / D D / Y Y Y Y)

13. DATE DEVICE CEASED BEING MARKETED *(If applicable)* __ __ / __ __ / __ __ __ __ (M M / D D / Y Y Y Y)

14. IS THE DEVICE THE SUBJECT OF AN APPROVED POST MARKET (522) STUDY?
☐ Yes ☐ No

15. NUMBERS OF THIS DEVICE

	Number		
a. Manufactured in the last 12 months			
b. Distributed in the last 12 months		☐ Actual	☐ Estimated
c. In current use		☐ Actual	☐ Estimated

NOTE: *Attach a copy of the method used to estimate the numbers in 15.b./15.c. OR if the method has been submitted in a previous baseline report complete item 16. below.*

16. IF THE METHOD USED TO ESTIMATE THE NUMBERS IN 15.b. and/or 15.c. ABOVE HAS BEEN SUBMITTED IN A PREVIOUS BASELINE REPORT, COMPLETE THE FOLLOWING:

	ID for device in prior baseline report	***Date of previous baseline***
Distribution Estimation Method		__ __ / __ __ / __ __ __ __ (M M / D D / Y Y Y Y)
Current Use Estimation Method		__ __ / __ __ / __ __ __ __ (M M / D D / Y Y Y Y)