6.3 Summary of Safety and Effectiveness

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Applicant Name:
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Phone: 540-869-8158
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Establishment Registration Number: 1181121

Identification of Device:
Device Name: ARCHITECT® *STAT* CK-MB immunoassay
Proprietary/Trade Name: ARCHITECT® *STAT* CK-MB immunoassay
Common Name: CK-MB test system
Device Classification: Class II
Governing Regulation: 21 CFR 862.1215
FDA Panel: Clinical Chemistry
Product Code: ~~MMI~~ JTX

Identification of Predicate Device:
Abbott AxSYM® CK-MB Assay (K935924)

Intended Use of the Device:
ARCHITECT *STAT* CK-MB is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of CK-MB in human serum and plasma on the ARCHITECT *i* System with STAT capability. CK-MB values are used to assist in the diagnosis of myocardial infarction (MI).

Description of the Device:
The ARCHITECT ***STAT*** CK-MB assay is a two-step assay to determine the presence of the MB isoenzyme of creatine kinase (CK-MB) in human serum and plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex®.

In the first step, sample and anti-CK-MB coated paramagnetic microparticles are combined. After incubation and washing, anti-CK-MB acridinium conjugate is added in the second step. Following another incubation and wash, pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). A direct relationship exists between the amount of CK-MB in the sample and the RLUs detected by the ARCHITECT *i** optical system.

Comparison of Technological Characteristics:

The ARCHITECT® *STAT* CK-MB and the AxSYM® CK-MB assays use a microparticle immunoassay method for the quantitative determination of creatine kinase (CK-MB) in human serum or plasma. Values obtained are used to assist in the diagnosis of

myocardial infarction. Anti-microbial agent is used as a preservative for all reagent components (microparticles and conjugate) of the AxSYM® CK-MB assay as well as the ARCHITECT *STAT* CK-MB. Both assays have microparticles coated with mouse monoclonal anti-CK-MB in TRIS buffer.

CK-MB is an 84,000 molecular weight enzyme that represents a significant fraction of the creatine kinase present in myocardial tissue. CK-MB is also present in a variety of other tissues, although at much lower levels. The appearance of CK-MB in serum, in the absence of major muscle trauma, may be indicative of cardiac damage and thus, myocardial infarction (MI). MI is defined as myocardial cell death due to prolonged ischemia. The magnitude and temporal course of CK-MB elevation and decline may clarify the timing of the myocardial insult, allow an estimate of infarct size, and contribute to the non-invasive assessment of reperfusion.

Summary of Non-clinical Performance:

The ARCHITECT® *STAT* CK-MB assay is substantially equivalent to the Abbott AxSYM® CK-MB assay in terms of precison, linearity, interferences, and stability as demonstrated in non-clinical performance data in this 510(k) submission.

Summary of Clinical Performance:

The ARCHITECT *STAT* CK-MB assay demonstrated substantially equivalent to the AxSYM® CK-MB assay. The sample stability study evaluated ARCHITECT *STAT* CK-MB assay using Lithium Heparin and Serum Separator collection tubes. There was no systematic gain or loss of the detectability of CK-MB in serum or plasma samples under any of the storage conditions evaluated in this study. A method comparison using the NCCLS Bias Estimation Standard (EP-9A) was also conducted with the ARCHITECT *STAT* CK-MB and AxSYM® CK-MB assays and as a result, the two systems demonstrated substantial equivalence as indicated by clinical data in this 510(k) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 21 2004

Ms. Josefina Infantas, MSM
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PO Box 307
Middletown, VA 22645

Re: k041596
Trade/Device Name: ARCHITECT® *STAT* CK-MB Immunoassay
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: JHX, JIS
Dated: June 10, 2004
Received: June 14, 2004

Dear Ms. Infantas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

6.1 Indications for Use

ARCHITECT ***STAT*** CK-MB is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of CK-MB in human serum and plasma on the ARCHITECT *i* System with STAT capability. CK-MB values are used to assist in the diagnosis of myocardial infarction (MI).

510 (k) Number (if known): K041596

Device Name: ARCHITECT® *STAT* CK-MB Immunoassay

Prescription Use (Part 21 CFR 801 Subpart D) ___x___ AND/OR Over-The-Counter Use (21 CFR 807 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K041596