K041192

AUG 1 2 2004

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## 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:**
Josefina Infantas, MSM
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Fisher Diagnostics
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**Establishment Registration Number:** 1181121

**Identification of Device:**
Device Name: ARCHITECT® *STAT* Troponin-I immunoassay
Proprietary/Trade Name: ARCHITECT® *STAT* Troponin-I immunoassay
Common Name: Troponin-I test system
Device Classification: Class II
Governing Regulation: 21 CFR 862.1215
FDA Panel: Clinical Chemistry (75)
Product Code: MMI

**Identification of Predicate Device:**
Access® AccuTnI Assay (K021814)

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

**Description of the Device:**
The ARCHITECT *STAT* Troponin-I assay is a two-step assay to determine the presence of cardiac troponin-I in human serum and plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex®.

In the first step, sample, assay diluent and anti-troponin-I antibody-coated paramagnetic microparticles are combined. After incubation and washing, anti-troponin-I acridinium labeled 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 troponin-I in the sample and the RLUs detected by the ARCHITECT *i* system optics. The concentration of troponin-I is read

relative to a standard curve established with calibrators of known troponin-I concentration.

**Comparison of Technological Characteristics:**

The ARCHITECT® *STAT* Troponin-I and the ACCESS® AccuTnI assays use a chemiluminescent microparticle immunoassay (CMIA) method for the quantitative determination of cardiac troponin-I in human serum and plasma. Values obtained are used to assist in the diagnosis of myocardial infarction. Proclin® 300 is a preservative used all reagent components (microparticles, diluent and conjugate) of the ACCESS AccuTnI assay, while only the diluent and conjugate of the ARCHITECT *STAT* Troponin-I contain Proclin® 300 as a preservative. The ARCHITECT *STAT* Troponin-I microparticles contain an antimicrobial agent as a preservative. Both assays have microparticles coated with mouse monoclonal anti-troponin-I in TRIS buffer. The conjugates both contain mouse monoclonal anti-troponin-I.

**Summary of Non-clinical Performance:**

The ARCHITECT® *STAT* Troponin-I assay is substantially equivalent to the ACCESS® AccuTnI 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* Troponin-I assay demonstrated sensitivity and specificity that is substantially equivalent to the ACCESS AccuTnI assay, using the optimal AMI "cut-off" of 0.30 ng/mL as indicated by clinical data in this 510(k) submission. The sample stability study evaluated ARCHITECT *STAT* Troponin-I assay using Lithium Heparin and Serum Separator collection tubes. There was no systematic gain or loss of the detectability of troponin-I in serum or plasma samples under any of the storage conditions evaluated in this study. A method comparison was also conducted with the ARCHITECT *STAT* Troponin-I and ACCESS AccuTnI assays and as a result, the two systems demonstrated substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 1 2 2004

Ms. Josefina Infantas, MSM
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8365 Valley Pike
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Re: k041192
Trade/Device Name: ARCHITECT® *STAT* Troponin-I Immunoassay
ARCHITECT *STAT* Troponin- I Calibrators
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: MMI, JIT
Dated: August 5, 2004
Received: August 5, 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

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

The ARCHITECT *STAT* Troponin-I Calibrators are for calibration of the ARCHITECT *i* 2000SR System when used for the quantitative determination of cardiac Troponin-I in human serum or plasma.

510 (k) Number (if known): K041192

Device Name: ARCHITECT® *STAT* Troponin-I 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol C. Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K041192