K042924

JAN 24 2005

7.3 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
Sr. Regulatory Affairs Specialist
Fisher Diagnostics
8365 Valley Pike
P.O. Box 307
Middletown, VA 22645
Phone: 540-974.1082
Fax: 973.257.2611

Establishment Registration Number: 1181121

Identification of Device:
Device Name: ARCHITECT® *STAT* MYO immunoassay
Proprietary/Trade Name: ARCHITECT® *STAT* MYO immunoassay
Common Name: MYO test system
Device Classification: Class II
Governing Regulation: 21 CFR 866.5680
FDA Panel: Clinical Chemistry
Product Code: MVE

Identification of Predicate Device:
Abbott AxSYM® MYO Assay (K983848)

Intended Use of the Device:
ARCHITECT® *STAT* MYO is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of MYO in human serum and plasma on the ARCHITECT® *i* System with STAT protocol capability.

Description of the Device:

The ARCHITECT® *STAT* Myoglobin assay is a two-step immunoassay for the quantitative determination of myoglobin in human serum and plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex®. In the first step, sample and anti-myoglobin coated paramagnetic microparticles are combined and incubated. Myoglobin present in the sample binds to the anti-myoglobin coated microparticles. After washing, antimyoglobin 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 myoglobin in the sample and the RLUs detected by the
ARCHITECT® *i** system optics.
* *i* = immunoassay

7.4 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

The ARCHITECT® *STAT* MYO and the AxSYM® MYO assays use a microparticle immunoassay method for the quantitative determination of myoglobin (MYO) in human serum or plasma. Anti-microbial agent is used as a preservative for all reagent components (microparticles and conjugate) of the AxSYM® MYO assay as well as the ARCHITECT® *STAT* MYO. Both assays have microparticles coated with mouse monoclonal anti-MYO in TRIS buffer.

Myoglobin is a tightly folded, globular heme-protein located in the cytoplasm of both skeletal and cardiac muscle cells. Its function is to store and supply oxygen to muscle cells. The molecular weight of myoglobin is approximately 17,800 daltons.[1,2] The relatively low molecular weight and the location of storage accounts for the rapid release from damaged muscle cells and earlier rises in concentration measured above baseline in blood as compared to other cardiac markers.[1,3,4]
In ischemic heart disease, such as myocardial infarction (MI), a temporal pattern of increased release of myoglobin into the blood stream is observed. The serum or plasma myoglobin level will start to show an increase between 2-4 hours after an MI has occurred, peaking at approximately 8-10 hours, and returning to baseline after 24 hours. Measurement of myoglobin between 2-12 hours after an MI can be a good adjunct to electrocardiography (ECG) in improving the efficiency of early diagnosis of MI.[1,5,6] Monitoring the myoglobin levels can also help in evaluating the success of thrombolytic therapy.[6,7]
Since myoglobin is present in both cardiac and skeletal muscle, any damage to either of these muscle types results in its release into the blood stream. Elevated serum levels of myoglobin have been observed under the following conditions: skeletal muscle damage, skeletal muscle or neuromuscular disorders, cardiac bypass surgery, renal failure, strenuous exercise.[2,5,8]
Therefore, serum myoglobin levels should be used in conjunction with other aspects of the patient assessment to aid in the diagnosis of an MI. Myoglobin may also rise moderately above the reference range in chronic ischemic heart disease (i.e. unstable angina).[2] For diagnostic purposes, the ARCHITECT® *STAT* Myoglobin assay results should be used in conjunction with other data; e.g., other clinical testing, ECG, symptoms, clinical observations.[8].

7.5 SUMMARY OF NON-CLINICAL PERFORMANCE:

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

7.6 SUMMARY OF CLINICAL PERFORMANCE:

The ARCHITECT® *STAT* MYO assay demonstrated substantially equivalent to the AxSYM® MYO assay. The sample stability study evaluated ARCHITECT® *STAT* MYO assay using Lithium Heparin and Serum Separator collection tubes. There was no systematic gain or loss of the detectability of MYO 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 MYO and AxSYM® MYO 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

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 24 2005

Ms. Josefina Infantas
Sr. Regulatory Affairs Specialist
Fisher Diagnostics
8365 Valley Pike
PO Box 307
Middletown, VA. 22645

Re: k042924
Trade/Device Name: ARCHITECT®STAT Myoglobin Immunoassay
Regulation Number: 21 CFR 866.5680
Regulation Name: Myoglobin immunological test system
Regulatory Class: Class II
Product Code: DDR, JIS
Dated: December 22, 2004
Received: January 3, 2005

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 (240)276-0484. 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/industry/support/index.html

Sincerely yours,

Carol C Benson for

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

Indications for Use

510(k) Number: k042924

Device Name: ARCHITECT® STAT Myoglobin Immunoassay

Indications For Use: ARCHITECT STAT MYOGLOBIN is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of Myoglobin in human serum and plasma on the ARCHITECT i System with STAT protocol capability. Myoglobin values are used to assist in the diagnosis of myocardial infarction (MI).

The ARCHITECT STAT MYOGLIBIN Calibrators are for the calibration of the ARCHITECT i System with STAT protocol capability when used for the quantitative determination of myoglobin in human serum or plasma.

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 C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K042924