SEP 1 1 2008

ARCHITECT *i*Phenytoin

510(k) Summary (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 and 21 CFR 807.92.

The assigned 510(k) number is: K080696

Preparation Date: _____

Applicant Name:
Carol Jochum
Senior Regulatory Affairs Specialist
100 Abbott Park Rd
Abbott Park, IL 60064
Carol.Jochum@abbott.com

Device Name:
Reagents
Classification Name: Diphenylhydantoin test system
Trade Name: ARCHITECT *i*Phenytoin Immunoassay
Common Name: Diphenylhydantoin test
Governing Regulation: 862.3350
Device Classification: Class II
Classification Panel: Toxicology
Product Code: LGR

Calibrators:
Classification Name: Calibrator, drug specific
Trade Name: ARCHITECT *i*Phenytoin Calibrators (A-F)
Common Name: Calibrator
Governing Regulation: 862.3200
Device Classification: Class II
Classification Panel: Toxicology
Product Code: DLJ

Legally marketed device to which equivalency is claimed:

AxSYM Phenytoin (K935375)

Intended Use of Device:
The ARCHITECT *i*Phenytoin assay is an *in vitro* chemiluminescent microparticle immunoassay (CMIA) for the quantitative measurement of phenytoin, an anticonvulsant drug, in human serum or plasma on the ARCHITECT *i* System with *STAT* protocol capability. The measurements obtained are used in monitoring levels of phenytoin to help ensure appropriate therapy.

Description of Device:
The ARCHITECT *i*Phenytoin assay is a one-step *STAT* immunoassay for the quantitative measurement of phenytoin in human serum or plasma using CMIA technology, with flexible assay protocols, referred to as Chemiflex.

Sample, anti-phenytoin coated paramagnetic microparticles, and phenytoin acridinium-labeled conjugate are combined to create a reaction mixture. The anti-phenytoin coated microparticles bind to phenytoin present in the sample and to the phenytoin acridinium-labeled conjugate. After washing, pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). An indirect relationship exists between the amount of phenytoin in the sample and the RLUs detected by the ARCHITECT *i* System optics.

Comparison of Technological Characteristics:
The ARCHITECT *i*Phenytoin assay is a chemiluminescent microparticle immunoassay (CMIA) method for the quantitative measurement of phenytoin, an anticonvulsant drug, in human serum and plasma. The AxSYM Phenytoin assay utilizes fluorescence polarization immunoassay (FPIA) technology for the measurement of phenytoin, an anticonvulsant drug, in serum or plasma.

Summary of Non-Clinical Performance:
The ARCHITECT *i*Phenytoin assay is substantially equivalent to the AxSYM Phenytoin assay in terms of precision, linearity and interferences as demonstrated in non-clinical performance data in this 510(k) submission.

Summary of Clinical Performance:
The ARCHITECT *i*Phenytoin demonstrated substantially equivalent performance to the AxSYM Phenytoin with a correlation coefficient of 0.993.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Abbott Laboratories
c/o Ms. Carol Jochum
Senior Regulatory Affairs Specialist
100 Abbott Park Road
AP6C-2; Dept. 049C
Abbott Park, IL 60064

Re: k080696
Trade/Device Name: Architect *i*Phenytoin Immunoassay
Regulation Number: 21 CFR 862.3350
Regulation Name: Diphenylhydantoin test system
Regulatory Class: Class II
Product Code: DIP, LGR
Dated: August 25, 2008
Received: August 26, 2008

Dear Ms. Jochum:

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) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., 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

Indication for Use

510(k) Number (if known): k080696

Device Name: ARCHITECT *i*Phenytoin

Indication for Use:

Reagents

The ARCHITECT *i*Phenytoin assay is an *in vitro* chemiluminescent microparticle immunoassay (CMIA) for the quantitative measurement of phenytoin, an anticonvulsant drug, in human serum or plasma on the ARCHITECT *i* System with *STAT* protocol capability. The measurements obtained are used in monitoring levels of phenytoin to help ensure appropriate therapy.

Calibrators

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

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) And/Or Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k080696