ThermoFisher
SCIENTIFIC

OCT 17 2007

510(k) SUMMARY

This Summary of 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: _k063145_____

A. Introduction:

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

B. Submitter

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Contact: Päivi Sormunen, Vice President of QRC
Date of Preparation: September 25, 2007

C. Device name

Proprietary name: Phenytoin
Common name: Phenytoin Test System
Classification: II
Class: Toxicology
Product Code: DIP

Proprietary name: TDM Calibration set B
Common name: Calibrator
Classification: II
Class: Toxicology
Product Code: DKB

D. Intended Use

Phenytoin

For *in vitro* diagnostic use in the quantitative determination of the phenytoin concentration in human serum on T60 analyzer. Measurements are used in the diagnosis and treatment of phenytoin overdose and in monitoring levels of phenytoin to help ensure proper therapy.

TDM Calibration set B

For *in vitro* diagnostic use as a calibrator in the quantitative measurement of the kit code 981647 Phenytoin assay on T60 Analyzer

E. Indications for use

Phenytoin is intended for quantitative in-vitro diagnostic determination of the phenytoin concentration in human serum using T60 Clinical Chemistry Analyzers. Measurements are used in the diagnosis and treatment of phenytoin overdose and in monitoring levels of phenytoin to help ensure proper therapy.

For TDM Calibration set B, see intended use.

F. Substantial Equivalence

Microgenics Corporation item:
The CEDIA® Phenytoin II

G. Substantial equivalence –similarities

Phenytoin is substantially equivalent to other devices legally marketed in United States. We claim equivalence to the Microgenics Corporation item, the CEDIA® Phenytoin II

H. The following table compares the Phenytoin with the predicate assay

Table 1
Phenytoin

Attribute	**New device #1**	**Predicate device #1**
Intended Use	For *in vitro* diagnostic use in the quantitative determination of the phenytoin concentration in human serum on T60 analyzer. Measurements are used in the diagnosis and treatment of phenytoin overdose and in monitoring levels of phenytoin to help ensure proper therapy	The CEDIA® Phenytoin II homogeneous enzyme immunoassay is for the quantitation of phenytoin in human serum or plasma using automated clinical chemistry analyzers. Measurements are used in the diagnosis and treatment of phenytoin overdose and in monitoring levels of phenytoin to ensure proper therapy.
Indication for Use	Phenytoin is intended for quantitative in-vitro diagnostic determination of the phenytoin concentration in human serum using T60 Clinical Chemistry Analyzers. Measurements are used in the diagnosis and treatment of phenytoin overdose and in monitoring levels of phenytoin to help ensure proper therapy.	See Intended Use
Assay Protocol	Assay uses recombinant DNA technology (US Patent no. 4708929) to produce a unique homogeneous enzyme immunoassay system.	Assay uses recombinant DNA technology (US Patent no. 4708929) to produce a unique homogeneous enzyme immunoassay system.
Traceability/Standardization	The calibration values are traceable to USP reference materials prepared gravimetrically to drug-free human serum.	-
Sample Type	Serum	Serum or plasma (Na or Li heparin, Na EDTA)
Reagent Storage	The unopened reagents are stable at 2…8 °C until the expiration date stated on the label. Refer to the Application Notes of your T60 analyzer for the on board stability of reagents. DO NOT FREEZE the unopened reagents or the reconstituted reagents.	Store CEDIA® Phenytoin II reagents at 2-8 °C. Do not freeze. For stability of the unopened components refer to the box or bottle labels for the expiration date

Attribute	New device #1	Predicate device #1
Expected Values	Therapeutic range for adults: 10 – 20 µg/ml or 40 – 79 µmol/l (1,2)	**Therapeutic range:** 10 – 20 µg/ml for adults 6 – 14 µg/ml for children
Instrument	T60 and DPC T60i, DPC T60i Kusti	Roche Hitachi 912
Measuring Range	0.8 – 38 µg/ml (3.2 – 150 µmol/l)	Between 0.6 µg/ml and the value of the Core TDM Multi-Cal High Calibrator (approximately 40 µg/ml or 158.4 µmol/l)
Precision	**Within run** Level 8.6 µg/ml SD = 0.20 CV(%) = 2.4 Level 20.0 µg/ml SD = 0.32 CV(%) = 1.6 **Between run** Level 8.6 µg/ml SD = 0.15 CV(%) = 1.7 Level 20.0 µg/ml SD = 0.23 CV(%) = 1.2 **Total** Level 8.6 µg/ml SD = 0.39 CV(%) = 4.5 Level 20.0 µg/ml SD = 0.59 CV(%) = 3.0	**Within run** Level 6.3 µg/ml SD = 0.20 CV(%) = 3.2 Level 14.8 µg/ml SD = 0.29 CV(%) = 2.0 Level 26.8 µg/ml SD = 0.35 CV(%) = 1.3 **Total** Level 6.3 µg/ml SD = 0.32 CV(%) = 5.1 Level 14.8 µg/ml SD = 0.46 CV(%) = 3.1 Level 26.8 µg/ml SD = 0.60 CV(%) = 2.3
Method Comparison	(Unit µg/ml) (Deming): y = 1.00x – 0.8 r = 0.995 Range 1.3 – 38.3 µg/ml N = 70	**Previous CEDIA® Phenytoin assay (x). Correlation (µg/ml)** (Deming's): Y =1.00x -0.19 r = 0.998 Sy.x = 0.39 Range 0.7 – 35.1 µg/ml N = 114

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Attribute	New device #1	Predicate device #1
Limitations	No interference found Bilirubin: up to 58 mg/dl (1000 µmol/l) Hemoglobin: up to 1000 mg/dl (10 g/l) Lipemia: up to 1000 mg/dl (10 g/l) of Intralipid®	**Ikterus:** No significant interference from bilirubin up to I index of 60 (approximate bilirubin concentration: 60 mg/dl) **Hemolysis:** No significant interference from hemoglobin up to H index of 1000 (approximate hemoglobin concentration: 1000 mg/dl) **Lipemia (Intralipid®):** No significant interference from lipemia up to L index of 1000 (approximate triglycerides concentration: 2000 mg/dl). No significant interference from total protein up to 12 g/dl. No significant interference from rheumatoid factor up to 100 IU/ml.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
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OCT 17 2007

Re: k063145
Trade/Device Name: Phentoin, TDM Calibration Set B
Regulation Number: 21 CFR 862.3350
Regulation Name: Diphenylhydantoin test system
Regulatory Class: Class II
Product Code: DIP, DKB
Dated: September 25, 2007
Received: September 27, 2007

Dear Ms. Sormunen:

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

Indications for Use

510(k) Number (if known): k063145

Device Names: **Phenytoin**
TDM Calibration set B

Indications for Use:

Phenytoin is intended for quantitative *in vitro* diagnostic determination of the phenytoin concentration in human serum using T60 Clinical Chemistry Analyzers. Measurements are used in the diagnosis and treatment of phenytoin overdose and in monitoring levels of phenytoin to help ensure proper therapy.

TDM Calibration set B is intended for *in vitro* diagnostic use as a calibrator in the quantitative measurement of the kit code 981647 Phenytoin assay on T60 Analyzer.

Prescription Use X And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 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) k063145