ThermoFisher
SCIENTIFIC

OCT 5 ° 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: k063131

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

Thermo Fisher Scientific Oy
Ratastie 2
P.O. Box 100
FIN-01621 Vantaa
Finland
+358 (9) 329 100 tel
+358 (9) 3291 0500 fax
Contact: Päivi Sormunen, Vice President of QRC
Date of Preparation: September 25, 2007

C. Device name

Proprietary name: Carbamazepine
Common name: Carbamazepine test system
Classification: II
Class: Toxicology
Product Code: KLT

Proprietary name: Valproic Acid
Common name: Valproic Acid test system
Classification: II
Class: Toxicology
Product Code: LEG

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

D. Intended Use

Carbamazepine

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

Valproic Acid

For *in vitro* diagnostic use in the quantitative determination of the valproic acid concentration in human serum on T60 instrument. Measurements are used in the diagnosis and treatment of valproic acid overdose and in monitoring levels of valproic acid 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 981645 Carbamazepine and kit code 981650 Valproic acid assays on T60 Analyzer.

E. Indications for use

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

The Valproic Acid is intended for the quantitative *in vitro* diagnostic determination of the valproic acid concentration in human serum using T60 Clinical Chemistry Analyzers. Measurements are used in the diagnosis and treatment of valproic acid overdose and in monitoring levels of valproic acid 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 981645 Carbamazepine and kit code 981650 Valproic acid assays on T60 Analyzer.

F. Substantial Equivalence

CEDIA® Carbamazepine II
Microgenics Corporation

CEDIA® Valproic acid II
Microgenics Corporation

G. Substantial equivalence -similarities

T60 Carbamazepine and Valproic Acid are substantially equivalent to other devices legally marketed in United Staes. We claim equivalence to the Microgenics Corporation CEDIA® Carbamazepine II and CEDIA® Valproic acid II

The following table compares the Carbamazepine with the predicate test system

Attribute	**New device #1**	**Predicate device #1**
Intended Use	For *in vitro* diagnostic use in the quantitative determination of the carbamazepine concentration in human serum on T60 analyzer. Measurements are used in the diagnosis and treatment of carbamazepine overdose and in monitoring levels of carbamazepine to help ensure proper therapy.	The CEDIA® Carbamazepine II homogeneous enzyme immunoassay is for the quantitation of carbamazepine in human serum or plasma using automated clinical chemistry analyzers. Measurements are used in the diagnosis and treatment of carbamazepine overdose and in monitoring levels of carbamazepine to ensure proper therapy.
Indication for Use	The Carbamazepine is intended for the quantitative *in vitro* diagnostic determination of the carbamazepine concentration in human serum using T60 Clinical Chemistry Analyzers. Measurements are used in the diagnosis and treatment of carbamazepine overdose and in monitoring levels of carbamazepine to help ensure proper therapy.	See Intended Use
Assay Protocol	Assay uses recombinant DNA technology (US Patent no. 4708929) to produce a unique homogenous enzyme immunoassay system.	Assay uses recombinant DNA technology (US Patent no. 4708929) to produce a unique homogenous enzyme immunoassay system.
Traceability/Standardization	The calibration values are traceable to USP reference materials prepared gravimetrically to drug-free human serum.	The calibration values are traceable to USP reference materials prepared gravimetrically to drug-free human serum.
Sample Type	Human 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 Carbamazepine 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: According to different sources the suggested ranges are: 4 - 12 µg/ml or 17 - 51 µmol/l (1) 4 - 10 µg/ml or 17 - 42 µmol/l (2)	**Therapeutic Range** (µg/ml) Penry and Newmark 5-12 Scheuer and Pedley 8-12 Troupin *et al* 8-12 Strandjord and Johannessen 3-12 Simonsen *et al* 6-10 Larkin *et al* 4-10 Shorvon *et al* 4-8 MacKichan and Kutt 4-12
Instrument	T60, DPC T60i, and DPC T60i Kusti	Roche Hitachi 911/912
Measuring Range	From 1.0 µg/ml to 19.0 µg/ml.	Between 0.5 µg/ml and the value of the Core TDM Multi-Cal High Calibrator (approximately 20 µg/ml or 84.6 µmol/l).
Precision	**Within run** Level 3.0 µg/ml SD = 0.09 CV(%) = 2.8 Level 9.5 µg/ml SD = 0.14 CV(%) = 1.5 Level 15.0 µg/ml SD = 0.16 CV(%) = 1.1 **Between run** Level 3.0 µg/ml SD = 0.07 CV(%) = 2.4 Level 9.5 µg/ml SD = - CV(%) = - Level 15.0 µg/ml SD = 0.14 CV(%) = 0.9 **Total** Level 3.0 µg/ml SD = 0.19 CV(%) = 6.3 Level 9.5 µg/ml SD = 0.32 CV(%) = 3.3 Level 15.0 µg/ml SD = 0.42 CV(%) = 2.8	**Within run** Level 4.2 µg/ml SD = 0.06 CV(%) =1.5 Level 10.6 µg/ml SD = 0.08 CV(%) = 0.8 Level 16.8 µg/ml SD = 0.12 CV(%) = 0.7 **Total** Level 4.2 µg/ml SD = 0.15 CV(%) = 3.5 Level 10.6 µg/ml SD = 0.21 CV(%) = 2.0 Level 16.8 µg/ml SD = 0.29 CV(%) = 1.7

Attribute	New device #1	Predicate device #1
Method Comparison	(Unit µg/ml) Deming: y = 0.98 x + 0.02 r = 0.993 Range 1.9 - 19.6 µg/ml N = 134	**Previous CEDIA Carbamazepine assay (x). Correlation (µg/ml)** (Deming's): Y =1.04x -0.04 r = 0.999 Sy.x = 0.26 Range 1.3 – 19.8 µg/ml N = 103
Limitations	No interference found Hemoglobin: up to 1000 mg/dl (10 g/l). Bilirubin: up to 58 mg/dl (1000 µmol/l) Lipemia: up to 1000 mg/dl (10 g/l) of Intralipid®	Samples containing carbamazepine and the following concentrations of potential interference substances were quantitated accurately by the CEDIA® Carbamazepine II assay: Hemoglobin up to 1000 mg/dl, Bilirubin up to 66 mg/dl, Triglyceride up to 1000 mg/dl, Total protein up to 12 g/dl, Rheumatoid factor up to 180 IU/ml

The following table compares the Valproic Acid with the predicate test system

Attribute	**New device #1**	**Predicate device #1**
Intended Use	For *in vitro* diagnostic use in the quantitative determination of the valproic acid concentration in human serum on T60 instrument. Measurements are used in the diagnosis and treatment of valproic acid overdose and in monitoring levels of valproic acid to help ensure proper therapy.	The CEDIA® Valproic Acid II homogeneous enzyme immunoassay is for the quantitation of valproic acid in human serum or plasma using automated clinical chemistry analyzers. Measurements are used as an aid in the diagnosis and treatment of valproic acid overdose and in monitoring levels of valproic acid to ensure proper therapy.
Indication for Use	The Valproic Acid is intended for the quantitative *in vitro* diagnostic determination of the valproic acid concentration in human serum using T60 Clinical Chemistry Analyzers. Measurements are used in the diagnosis and treatment of valproic acid overdose and in monitoring levels of valproic acid to help ensure proper therapy.	See Intended Use
Assay Protocol	Assay uses recombinant DNA technology (US Patent no. 4708929) to produce a unique homogenous enzyme immunoassay system.	Assay uses recombinant DNA technology (US Patent no. 4708929) to produce a unique homogenous enzyme immunoassay system.
Traceability/Standardization	The calibration values are traceable to USP reference materials prepared gravimetrically to drug-free human serum.	The calibration values are traceable to USP reference materials prepared gravimetrically to drug-free human serum.
Sample Type	Human 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. DO NOT FREEZE the unopened reagents or the reconstituted reagents.	Store CEDIA® Valproic acid 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: 50 - 100 µg/ml or 347 - 693 µmol/l (1,2)	**Therapeutic** Schobben *et al* 50-100 µg/ml Cloyd and Leppik 50-100 µg/ml Klotz and Schweizer 40-90 µg/ml Turnbull *et al* 50-100 µg/ml **Toxic** Schobben *et al* - µg/ml Cloyd and Leppik >100 µg/ml Klotz and Schweizer - Turnbull *et al* >100 µg/ml
Instrument	T60, DPC T60i, and DPC T60i Kusti	Roche Hitachi 911/912
Measuring Range	From 3.0 µg/ml to 142.5 µg/ml.	Between 3.0 µg/ml and the value of the Core TDM High Calibrator (approximately 150 µg/ml or 1039.5 µmol/l)
Precision	**Within run** Level 35.0 µg/ml SD = 0.43 CV(%) = 1.2 Level 81.1 µg/ml SD = 0.81 CV(%) = 1.0 Level 113.6 µg/ml SD = 1.01 CV(%) = 0.9 **Between run** Level 35.0 µg/ml SD = 0.61 CV(%) = 1.8 Level 81.1 µg/ml SD = 1.08 CV(%) = 1.3 Level 113.6 µg/ml SD = 1.07 CV(%) = 0.9 **Total** Level 35.0 µg/ml SD = 1.90 CV(%) = 5.4 Level 81.1 µg/ml SD = 3.15 CV(%) = 3.9 Level 113.6 µg/ml SD = 3.11 CV(%) = 2.7	**Within run** Level 24.4 µg/ml SD = 0.59 CV(%) =2.4 Level 95.0 µg/ml SD = 1.43 CV(%) = 1.5 Level 136.8 µg/ml SD = 1.81 CV(%) = 1.3 **Total** Level 24.4 µg/ml SD(µg/ml) =0.83 CV(%) = 3.4 Level 95.0 µg/ml SD = 1.93 CV(%) = 2.0 Level 136.8 µg/ml SD = 2.48 CV(%) = 1.8

Attribute	New device #1	Predicate device #1
Method Comparison	(Unit µg/ml) Deming: y = 0.996 x + 1.4 r = 0.993 Range 3.2 - 143.4 µg/ml N = 136	Commercially available fluorescence polarization immunoassay (x) Correlation (µg/ml) (Linear regression): Y = 1.08x -0.61 r = 0.972 Sy.x = 7.042 Range 2.6 – 119.8 µg/ml N = 77
Limitations	No interference found Hemoglobin: up to 1000 mg/dl (10 g/l). Bilirubin: up to 58 mg/dl (1000 µmol/l) Lipemia: up to 1000 mg/dl (10 g/l) of Intralipid®	Samples containing valproic acid and the following concentrations of potential interference substances were quantitated accurately by the CEDIA Valproic Acid II assay: Hemoglobin up to 1000 mg/dl, Bilirubin up to 60 mg/dl, Triglyceride up to 1000 mg/dl, Total protein up to 10 g/dl, IgA up to 790 mg/dl IgG up to 4300 mg/dl, IgM up to 840 mg/dl and Rheumatoid factor up to 200 IU/ml

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Thermo Fisher Scientific Oy
c/o Mr. Päivi Sormunen
Vice President of QRC
Ratastie 2, P.O. Box 100
FIN-01621 Vantaa, Finland

OCT 5 ' 2007

Re: k063131
Trade Name: Carbamazepine, Valproic Acid and TDM Calibration set B
Regulation Number: 21 CFR 862.3645
Regulation Name: Neuroleptic drugs radioreceptor assay test system.
Regulatory Class: Class II
Product Code: KLT, LEG, DKB
Dated: September 25, 2007
Received: September 27, 2007

Dear Mr. 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): K063131

Device Names: **Carbamazepine**
Valproic Acid
TDM Calibration set B

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

The Valproic Acid is intended for the quantitative *in vitro* diagnostic determination of the valproic acid concentration in human serum using T60 Clinical Chemistry Analyzers. Measurements are used in the diagnosis and treatment of valproic acid overdose and in monitoring levels of valproic acid 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 981645 Carbamazepine and kit code 981650 Valproic acid assays on T60 Analyzer.

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

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K063131