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OCT - 9 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: K063705

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's information

Name:	Thermo Fisher Scientific Oy
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Contact person:	Päivi Sormunen, Vice President of QRC
Date of Preparation:	October 5, 2007

C. Device name

Proprietary name: Lithium Micro Volume Electrode
Common name: Lithium
Classification: II
Class: Toxicology
Product Code: NDW

Proprietary name: Theophylline
Common name: Theophylline
Classification: II
Class: Toxicology
Product Code: KLS

Proprietary name: ISE Calibrator 1, ISE Calibrator 2&3 (FDA Clearance number K061107)
Common name: Calibrator
Classification: II
Class: Clinical Chemistry (75)
Product Code: JIX

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

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D. Intended Use

Lithium

For *in vitro* diagnostic use in the quantitative determination of the lithium concentration in human serum on T60 analyzer.

Theophylline

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

ISE Calibrator 1 and ISE Calibrator 2&3

For *in vitro* diagnostic use in T60 analyzer. The ISE Calibrator 1 and 2&3 are intended for calibration of ion selective electrodes for quantitative measurements of potassium, sodium and chloride in serum or plasma and lithium in serum.

TDM Calibration set B

For *in vitro* diagnostic use as a calibrator in the quantitative measurement of the kit code 981649 Theophylline assay on T60 Analyzer.

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E. Indications for use

Lithium is intended for *in vitro* diagnostic use in the quantitative determination of the lithium concentration in human serum on T60 Clinical Chemistry Analyzers. Measurements are used as an aid in the management of individuals taking lithium for the treatment of mental disturbances, such as manic-depressive illness (bipolar disorder).

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

For ISE Calibrator 1, ISE Calibrator 2&3 and TDM Calibration set B see intended use

F. Substantial Equivalence

Thermo Electron, Australia/U.S.A
The Infinity™ Lithium Reagent for Olympus® Analysers. (K003583)

Microgenics Corporation item:
The CEDIA® Theophylline II Assay. (K961462)

G. Substantial equivalence –similarities

Lithium Micro Volume Electrode is substantially equivalent to other devices legally marketed in United Staes. We claim equivalence to the Thermo Electron Australia/U.S.A, The Infinity™ Lithium Reagent for Olympus® Analysers.

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

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

Table 1 Lithium

Lithium		
Attribute	**New device #1** **Lithium Micro Volume Electrode Calibrator part** **ISE Calibrator 1 and ISE Calibrator 2 & 3**	**Predicate device #1** **Infinity™ Lithium Reagent for Olympus®** (K003583) **Thermo Trace TR66002 Calibrator part** **Lithium Standard TR66901**
Intended Use	For *in vitro* diagnostic use in the quantitative determination of the lithium concentration in human serum on T60 analyzer.	Reagent for the quantitative determination of Lithium concentration in human serum and plasma on the Olympus AU400/AU600/AU640/AU2700/ AU5400 chemistry analysers.
Indication for Use	Lithium is intended for *in vitro* diagnostic use in the quantitative determination of the lithium concentration in human serum on T60 Clinical Chemistry Analyzers. Measurements are used as an aid in the management of individuals taking lithium for the treatment of mental disturbances, such as manic-depressive illness (bipolar disorder).	Lithium is widely used in the treatment of manic depressive psychosis.
Assay Protocol	Potentiometric	Spectrophotometric
Traceability/ Standardization	NIST SRM 924	-
Sample Type	Serum	Serum or EDTA-plasma
Reagent Storage	Calibrators in unopened bags or vials are stable at 2…30 °C until the expiration date printed on the label. Electrodes have to be stored at 2…8 °C before installation.	The unopened reagents are stable until the expiration date when stored at 2-8°C.
Expected Values	**Therapeutic range** According to source (1) suggested range is: 0.6 – 1.2 mmol/l Concentrations of 1.2 to 1.5 mmol/l signify a warning range and concentrations over 1.5 mmol/l indicate a significant risk of intoxication.	12 hour post dose trough concentration: 1.0 – 1.2 mmol/l Values >1.5 mmol/l 12 hours after dose indicates a significant risk of intoxication.

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Lithium		
Attribute	**New device #1** **Lithium Micro Volume Electrode Calibrator part ISE Calibrator 1 and ISE Calibrator 2 & 3**	**Predicate device #1** **Infinity™ Lithium Reagent for Olympus®** (K003583) **Thermo Trace TR66002 Calibrator part Lithium Standard TR66901**
Instrument	T60 and DPC T60i, DPC T60i Kusti	Olympus AU 400
Measuring Range	0.2 – 4.0 mmol/l	0.04 – 3.00 mmol/l
Precision	**Within run** Level 0.95 mmol/l SD = 0.008 CV(%) = 0.9 Level 1.86 mmol/l SD = 0.017 CV(%) = 0.9 **Between run** Level 0.95 mmol/l SD = 0.009 CV(%) = 0.9 Level 1.86 mmol/l SD =0.009 CV(%) = 0.5 **Total** Level 0.95 mmol/l SD =0.020 CV(%) = 2.1 Level 1.86 mmol/l SD = 0.039 CV(%) = 2.1	**Within run** Level 0.57 mmol/l SD = 0.005 CV(%) = 0.9 Level 1.83 mmol/l SD = 0.012 CV(%) = 0.7 **Total** Level 0.57 mmol/l SD =0.011 CV(%) = 1.9 Level 1.83 mmol/l SD = 0.024 CV(%) = 1.3
Method Comparison	(Unit mmol/l) (Deming): y =0.98x – 0.01 r = 0.999 Range 0.25 – 4.09 mmol/l N = 117	A comparison of this Lithium method (Method 1) vs NOVA ISE (Method 2) was run on AU600/AU640 r = 0.9956 y= 1.01x – 0.007 Range 0.11 – 1.73 mmol/l N = 55 serum samples

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Lithium		
Attribute	**New device #1** **Lithium Micro Volume Electrode Calibrator part ISE Calibrator 1 and ISE Calibrator 2 & 3**	**Predicate device #1** **Infinity™ Lithium Reagent for Olympus®** (K003583) **Thermo Trace TR66002 Calibrator part Lithium Standard TR66901**
Limitations	**Bilirubin** (conjugated): No interference found up to 41 mg/dl (700 µmol/l) of conjugated Bilirubin **Lipemia:** No interference found up to 1000 mg/dl (10 g/l) of Intralipid® **Hemolysate:** No interference found up to 1000 mg/dl (10 g/l) of hemoglobin.	Free Bilirubin: No significant interference from free bilirubin (<10% deviation) up to 769 µmol/l (45 mg/dl) Conjugated Bilirubin: No significant interference from conjugated bilirubin (<10% deviation) up to 769 µmol/l (45 mg/dl) Lipaemia: No significant interference from lipaemia (<10% deviation) measured as triglycerides, up to 22.6 mmol/l (2000 mg/dl) Haemoglobin: No interference from haemoglobin (<5% deviation) up to 2 g/l No significant interference (<5% deviation from assigned lithium concentration) from Sodium: Up to 200 mmol/l Potassium: Up to 8.00 mmol/l Calcium: Up to 4.00 mmol/l (16 mg/dl) Magnesium: Up to 2.00 mmol/l (4.86 mg/dl) Iron: Up to 200µmol/l (1117 µg/dl) Zinc: Up to 250 µmol/l (1625 µg/dl) Copper: Up to 250 µmol/l (1588 µg/dl)

The following table compares the Theophylline with the predicate assay

Table 2 Theophylline

Theophylline		
Attribute	**New device #2**	**Predicate device #2** (K961462)
Intended Use	For *in vitro* diagnostic use in the quantitative determination of the theophylline concentration in human serum on T60 analyzer. Measurements are used in the diagnosis and treatment of theophylline overdose and in monitoring levels of theophylline to help ensure proper therapy	The CEDIA® Theophylline II homogeneous enzyme immunoassay is for the quantitation of theophylline in human serum or plasma using automated clinical chemistry analyzers. Measurements are used in the diagnosis and treatment of theophylline overdose and in monitoring levels of theophylline to ensure proper therapy.
Indication for Use	Theophylline is intended for quantitative *in vitro* diagnostic determination of the theophylline concentration in human serum using T60 Clinical Chemistry Analyzers. Measurements are used in the diagnosis and treatment of theophylline overdose and in monitoring levels of theophylline to help ensure proper therapy.	The CEDIA® Theophylline II homogeneous enzyme immunoassay is for the quantitation of theophylline in human serum or plasma using automated clinical chemistry analyzers. Measurements are used in the diagnosis and treatment of theophylline overdose and in monitoring levels of theophylline to ensure proper therapy.
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® Theophylline 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

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Theophylline		
Attribute	**New device #2**	**Predicate device #2** (K961462)
Expected Values	**Therapeutic range** According to different sources the suggested ranges are: 8 – 20 µg/ml or 44 – 111 µmol/l (Asthma) (1,2) 10 – 20 µg/ml or 56 – 111 µmol/l (Asthma) (3) 5 – 10 µg/ml or 28 – 56 µmol/l (Apnea) (1)	**Therapeutic range:** 10 – 20 µg/ml in adults (asthma) 5 -10 µg/ml in newborns (apnea)
Instrument	T60 and DPC T60i, DPC T60i Kusti	Roche Hitachi 911/917
Measuring Range	From 1.4 µg/ml or 7.8 µmol/l to 40 µg/ml or 222 µmol/l.	Between 0.8 µg/ml and the value of the Core TDM Multi-Cal High Calibrator (approximately 40 µg/ml or 222 µmol/l)
Precision	**Within run** Level 4.4 µg/ml SD = 0.17 CV(%) = 3.9 Level 13.8 µg/ml SD = 0.21 CV(%) = 1.5 Level 28.1 µg/ml SD = 0.21 CV(%) = 0.8 **Between run** Level 4.4 µg/ml SD = 0.10 CV(%) = 2.2 Level 13.8 µg/ml SD = 0.18 CV(%) = 1.3 Level 28.1 µg/ml SD = 0.31 CV(%) = 1.1 **Total** Level 4.4 µg/ml SD = 0.35 CV(%) = 8.0 Level 13.8 µg/ml SD = 0.59 CV(%) = 4.3 Level 28.1 µg/ml SD = 0.87 CV(%) = 3.1	**Within run** Level 5.1 µg/ml SD = 0.17 CV(%) = 3.3 Level 15.1 µg/ml SD = 0.28 CV(%) = 1.9 Level 29.3 µg/ml SD = 0.39 CV(%) = 1.3 **Total** Level 5.1 µg/ml SD = 0.26 CV(%) = 5.1 Level 15.1 µg/ml SD = 0.36 CV(%) = 2.4 Level 29.3 µg/ml SD = 0.59 CV(%) = 2.0

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Theophylline		
Attribute	**New device #2**	**Predicate device #2** (K961462)
Method Comparison	(Unit µg/ml) (Deming): y = 0.989x + 0.05 r = 0.998 Range 1.1 – 37.7 µg/ml N = 133	Commercially available fluorescence polarization immunoassay (x). Correlation (µg/ml) (Deming's): y =1.01x -0.41 r = 0.997 Sy.x = 0.47 Range 0.9 – 37.4 µg/ml N = 125
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® Due to cross-reactivity with 1,3-Dimethyluric Acid, the Theophylline assay should not be used to quantitate samples from uremic patients.	**Ikterus:** No significant interference from bilirubin up to 66 mg/dl) **Hemolysis:** No significant interference from hemoglobin up to1000 mg/dl) **Lipemia (Intralipid®):** No significant interference from lipemia up to an L index of 1000 (approximate triglyceride concentration: 2000 mg/dl). No significant interference from total protein up to 12 g/dl. No significant interference from rheumatoid factor up to 180 IU/ml. Due to cross-reactivity with 1,3-Dimethyluric Acid, the Theophylline assay should not be used to quantitate samples from uremic patients.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT - 9 2007

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

Re: k063705
Trade/Device Name: Lithium Micro Volume Electrode, Theophylline, ISE Calibrator 1, ISE Calibrator 2&3, TDM Calibration set B
Regulation Number: 21 CFR 862.3560
Regulation Name: Lithium Test System
Regulatory Class: Class II
Product Code: NDW, KLS, JIX, 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 : k063705

Device Names: **Lithium Micro Volume Electrode**
Theophylline
ISE Calibrator 1
ISE Calibrator 2 & 3
TDM Calibration set B

Indications for Use:
Lithium is intended for *in vitro* diagnostic use in the quantitative determination of the lithium concentration in human serum on T60 Clinical Chemistry Analyzers. Measurements are used as an aid in the management of individuals taking lithium for the treatment of mental disturbances, such as manic-depressive illness (bipolar disorder).

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

The ISE Calibrators 1 and 2 & 3 are intended for calibration of ion selective electrodes for quantitative measurements of potassium, sodium and chloride in human serum or plasma and lithium in human serum. For the in vitro diagnostic use on the T60 analyzer.

TDM Calibration set B is intended for *in vitro* diagnostic use as a calibrator in the quantitative measurement of the kit code 981649 Theophylline assay 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) k063705