ThermoFisher
SCIENTIFIC

MAY 29 2008

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: K073295

A. Introduction:

According to the requirements of 21 CFR 807.92 the following information provides sufficent 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 Industrial Solutions and QRC
Date of Preparation:	November 19th, 2007

C. Device name

Proprietary name:	Urea / BUN, codes 981818 and 981820
Common name:	Urea nitrogen
Classification:	Clinical Chemistry
Class:	II
Product Code:	CDQ
Proprietary name:	sCal, code 981831
Common Name:	Calibrator, Multi-Analyte Mixture
Classification:	Clinical Chemistry
Class:	II
Product Code:	JIX
Proprietary name:	Nortrol, code 981043
Common Name:	Multi-analyte Controls (Assayed and unassayed)
Classification:	Clinical Chemistry
Class:	I
Product Code:	JJY
Proprietary name:	Abtrol, code 981044
Common Name:	Multi-analyte Controls (Assayed and unassayed)
Classification:	Clinical Chemistry
Class:	I
Product Code:	JJY

D. Intended Use

Urea / BUN

For *in vitro* diagnostic use in the quantitative determination of Urea / BUN (urea nitrogen) concentration in human serum or plasma on T60 instrument.

sCal, code 981831

For *in vitro* diagnostic use on T60 instrument. sCal is used as a multicalibrator for quantitative measurements using methods defined by Thermo Fisher Scientific Oy.

Nortrol

For *in vitro* diagnostic use for quantitative testing on T60 instrument. Nortrol is a control serum to monitor trueness and precision of the analytes listed in the separate Nortrol value sheet. The given values are valid for T60 Clinical Chemistry Instruments using methods defined by Thermo Fisher Scientific Oy.

Abtrol

For *in vitro* diagnostic use for quantitative testing on T60 instrument. Abtrol is a control serum to monitor trueness and precision of the analytes listed in the separate Abtrol value sheet. The given values are valid for T60 Clinical Chemistry Instruments using methods defined by Thermo Fisher Scientific Oy.

E. Indications for use

The Urea / BUN test system is intended for quantitative *in vitro* diagnostic measurement of Urea / BUN (urea nitrogen) concentration in human serum or plasma. Such measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.

For sCal Calibrator, Nortrol and Abtrol see intended use.

F. Substantial Equivalence

Bayer Corporation, model Bayer ADVIA 2400 Chemistry System.

Bayer Corporation item: Bayer ADVIA Urea nitrogen (UN) assay.

G. Substantial equivalence -similarities

Urea / BUN is substantially equivalent to other devices legally marketed in United States. We claim equivalence to the Bayer ADVIA Urea Nitrogen (UN) assay (K991576).

The following table compares the Urea / BUN with the predicate device
Table 1 (Results as urea nitrogen mg/dL).

Attribute	New device #1	Predicate device #1
Intended Use	For *in vitro* diagnostic use in the quantitative determination of Urea / BUN (urea nitrogen) concentration in human serum or plasma on T60 instrument.	For *in vitro* diagnostic use in the quantitative determination of urea nitrogen (an end product of nitrogen metabolism) in human serum, plasma (lithium heparin), and urine on the ADVIA Chemistry systems. Such measurements are used in the diagnosis and treatment of kidney disease, urinary tract obstruction, and acute or chronic renal failure.
Indication for Use	The Urea / BUN test system is intended for quantitative *in vitro* diagnostic measurement of urea / BUN (urea nitrogen) concentration in human serum or plasma. Such measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.	See intended use.
Assay Protocol	Urea is hydrolysed in the presence of water and urease to produce ammonia and carbon dioxide. In the presence of glutamate dehydrogenase (GLDH) and reduced nicotinamide adenine dinucleotide (NADH), the ammonia combines with a-ketoglutarate (α-KG) to produce L-glutamate. The resulting decrease in absorbance at 340 nm, as NADH is converted to NAD, is proportional to the level of urea in the sample.	Urea is hydrolyzed in the presence of water and urease to produce ammonia and carbon dioxide. The ammonia reacts with 2-oxoglutarate in the presence of glutamate dehydrogenase and NADH. The oxidation of NADH to NAD is measured as an inverse rate reaction at 340/410 nm.
Traceability/Standardization	The value of Urea / BUN has been assigned by using NIST SRM 909b as a primary reference	The ADVIA UN method is traceable to the CDC reference method, which uses reference materials from the National Institute of Standards and Technology (NIST). via patient sample correlation.

Attribute	New device #1	Predicate device #1
Sample Type	Serum, plasma (Li-heparin)	Serum, plasma (Li-heparin) and urine
Reagent Storage	Reagents in unopened vials are stable at 2…8 °C until the expiration date printed on the label.	For all systems, unopened reagents are stable until the expiration date printed on the product label when stored at 2° – 8°C. Do not freeze reagents.
Expected Values	**Serum**, adult: Urea Nitrogen: 6 - 20 mg/dl (2.2 - 7.2 mmol/l) Urea: 13 - 43 mg/dl (2.2 - 7.2 mmol/l)	**Serum:** 9 – 23 mg/dL (3.2 – 8.2 mmol/L) **Urine** 12 – 20 g/day (0.43 – 0.71 mol/day)
Instrument	T60 and DPC T60i, DPC T60i Kusti	ADVIA® 2400 Chemistry system.
Measuring Range	**Serum:** Urea nitrogen: 4.2 - 56 mg/dl (1.5 - 20.0 mmol/l) Urea: 9 – 120 mg/dl (1.5 - 20.0 mmol/l)	**Serum:** 5 – 150 mg/dL (1.8 – 53.6 mmol/L) **Urine:** 35 – 1000 mg/dL (12.5 – 357 mmol/L)

Attribute	New device #1	Predicate device #1
Precision	**Within run** Level 5.7 mg/dL SD= 0.2 CV(%)= 3.1 Level 14.7 mg/ dL SD= 0.2 CV(%)= 1.4 Level 24.7 mg/ dL SD= 0.4 CV(%)= 1.7 Level 44.8 mg/ dL SD= 0.4 CV(%)= 0.8 **Between run** Level 5.7 mg/dL SD= 0.4 CV(%)= 7.4 Level 14.7 mg/ dL SD= 0.1 CV(%)= 1.0 Level 24.7 mg/ dL SD= 0.4 CV(%)= 1.8 Level 44.8 mg/ dL SD= 0.4 CV(%)= 1.0 **Total** Level 5.7 mg/dL SD= 0.5 CV(%)= 8.1 Level 14.7 mg/ dL SD= 0.4 CV(%)= 2.7 Level 24.7 mg/ dL SD= 0.9 CV(%)= 3.6 Level 44.8 mg/ dL SD= 1.0 CV(%)= 2.2	**Serum:** **Within run** Level 19 mg/dL SD= 0.3 CV(%)= 1.4 Level 67 mg/dL SD= 0.3 CV(%)= 0.5 Level 81 mg/dL SD= 0.5 CV(%)= 0.7 **Total** Level 19 mg/dL SD= 0.4 CV(%)= 2.2 Level 67 mg/dL SD= 1.0 CV(%)= 1.5 Level81 mg/dL SD= 1.3 CV(%)= 1.6 **Urine:** **Within run** Level 453 mg/dL SD= 10.1 CV(%)= 2.2 Level 712 mg/dL SD= 28.6 CV(%)= 4.0 **Total** Level 453 mg/dL SD= 15.2 CV(%)= 3.4 Level 712 mg/dL SD= 30.6 CV(%)= 4.3

Attribute	New device #1	Predicate device #1
Method Comparison	Comparison to Bayer ADVIA 2400 y = 0.94x + 0.25 R = 0.996 range from 4.3 to 117.3 mg/dL N = 143	**Serum:** ADVIA 1650 y = 1.01x + 0.0 r = 1.000 N = 229 Range 5.1 –146.8 mg/dL Reference Method y = 1.04x - 0.1 r = 0.997 N = 50 Range 5.5 –136.2 mg/dL **Urine:** ADVIA 1650 y = 0.95x + 2.3 0.995 N = 51 Range 76.0 – 982.0 mg/dL
Limitations	**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 **Bilirubin, conjugated:** No interference found up to 58 mg/dL (1000 µmol/l) of conjugated bilirubin. **Bilirubin, unconjugated:** No interference found up to 58 mg/dL (1000 µmol/l) of unconjugated bilirubin.	**Lipemia (from Intralipid)**: No significant interference found up to 625 mg/dl of Intralipid. **Hemolysate:** No significant interference found up to 525 mg/dl of hemoglobin. **Bilirubin:** No significant interference found up to 30 mg/dl.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 29 2008

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

Re: k073295
Trade Name: Urea/Bun, sCal, Nortrol, Abtrol
Regulation Number: 21 CFR 862.1770
Regulation Name: Urea Nitrogen Test System
Regulatory Class: Class II
Product Codes: CDQ, JIX, JJY
Dated: March 20, 2008
Received: March 28, 2008

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

Indication for Use

510(k) Number (if known): K073295

Device Name: Urea / BUN, sCal, Nortrol, Abtrol

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For *in vitro* diagnostic use for quantitative testing on T60 instrument. Abtrol is a control serum to monitor trueness and precision of the analytes listed in the separate Abtrol value sheet. The given values are valid for T60 Clinical Chemistry Instruments using methods defined by Thermo Fisher Scientific Oy.

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)

Carol C Benson

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

510(k) K073295