K981123

APR 24 1998

510(k) Summary

Submitter's Name/Address
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Date of Preparation of this Summary: March 26, 1998

Device Trade or Proprietary Name: Urea

Device Common/Usual Name or Classification Name: Urea Nitrogen

Classification Number/Class: 75CDQ/Class II

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: K981123.

Test Description:

Urea Nitrogen is an *in vitro* diagnostic assay for the quantitative determination of urea nitrogen in human serum, plasma, or urine. The Urea Nitrogen assay is a clinical chemistry assay in which the the urea in the sample is hydrolyzed by urease to ammonia (NH_3) and carbon dioxide (CO_2). A second reaction, catalyzed by glutamate dehydrogenase (GLD), converts ammonia and α-ketoglutarate to glutamate and water with the concurrent oxidation of reduced nicotinamide adenine dinucleotide (NADH) to nicotinamide adenine dinucleotide (NAD). Two moles of NADH are oxidized for each mole of urea present. The initial rate of decrease in absorbance at 340 nm is proportional to the urea concentration in the sample.

Substantial Equivalence:

The Urea Nitrogen assay is substantially equivalent to the following devices:

- Roche® Cobas Mira® Plus Automated Chemistry System Urea Nitrogen assay (K954000) for the serum application
- Boehringer Mannheim® Urea Nitrogen assay on the Hitachi® 717 Analyzer (K771923) for the urine application

These assays yield similar Performance Characteristics.

Similarities to Roche:

- Both assays are *in vitro* clinical chemistry methods.
- Both assays can be used for the quantitative determination of urea nitrogen.
- Both assays yield similar clinical results.

Differences to Roche:

- There is a minor difference between the assay range.

Similarities to Boehringer Mannheim:

- Both assays are *in vitro* clinical chemistry methods.
- Both assays can be used for the quantitative determination of urea nitrogen.
- Both assays yield similar clinical results.

Differences to Boehringer Mannheim:

- There is a minor difference between the assay range

Intended Use:

The Urea Nitrogen assay is used for the quantitation of urea nitrogen in human serum, plasma, or urine.

Performance Characteristics:

Comparative performance studies were conducted using the ALCYON™ Analyzer. The Urea Nitrogen assay method comparison yielded acceptable correlation with the Roche Cobas Mira Plus Automated Chemistry System Urea Nitrogen assay for the serum application and the Boehringer Mannheim Urea Nitrogen assay on the Hitachi 717 Analyzer for the urine application. For the serum application, the correlation

coefficient = 0.9897, slope = 0.963, and Y-intercept = 1.206 mg/dL. For the urine application, the correlation coefficient = 0.9995, slope = 1.046, and Y-intercept = -1.208 mg/dL. Precision studies were conducted using the Urea Nitrogen assay. Within-run, between-run, and between-day studies were performed using two levels of control material. For the serum application, the total %CV for Level 1/Panel 111 is 4.9% and Level 2/Panel 112 is 3.9%. For the urine application, the total %CV for Level 1/Panel 111 control is 3.0% and Level 2/Panel 112 is 3.3%. The Urea Nitrogen assay is linear up to 120 mg/dL. The limit of quantititation (sensitivity) of the Urea Nitrogen assay is 1.8 mg/dL. These data demonstrate that the performance of the Urea Nitrogen assay is substantially equivalent to the performance of the Roche Cobas Mira Plus Automated Chemistry System Urea Nitrogen assay for the serum application and the Boehringer Mannheim Urea Nitrogen assay on the Hitachi 717 Analyzer for the urine application.

Conclusion:

The Urea Nitrogen assay is substantially equivalent to the Roche Cobas Mira Plus Automated Chemistry System Urea Nitrogen assay for the serum application and the Boehringer Mannheim Urea Nitrogen assay on the Hitachi 717 Analyzer for the urine application as demonstrated by results obtained in the studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 24 1998

Mark Littlefield
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Irving, Texas 75038

Re: K981123
Urea Nitrogen
Regulatory Class: II
Product Code: CDQ
Dated: March 26, 1998
Received: March 27, 1998

Dear Mr. Littlefield:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K981123

Device Name: Urea Nitrogen

Indications For Use:

The Urea Nitrogen assay is used for the quantitation of urea nitrogen in human serum, plasma, or urine. Measurements obtained by this device are used in diagnosis and treatment of certain renal and metabolic diseases.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981123