510(k) Summary

AUG - 2 2007

Submitter's Name/Address
SENTINEL CH.
Via Robert Koch, 2
20152 Milan - Italy

Contact Person
Fabio Rota
Technical Director
+39 02 3455148
Fax: +39 02 34551464

Date of Preparation of this Summary:	March 30, 2007
Device Trade or Proprietary Name:	Multigent Lithium
Device Common/Usual Name or Classification Name:	Lithium
Classification Number/Class:	NDW/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: K070987

Test Description:

The Multigent Lithium test is a spectrophotometric method, which can be readily adapted to automated clinical chemistry analyzers. Lithium present in the sample reacts with a substituted porphyrin compound at an alkaline pH, resulting in a change of absorbance, which is directly proportional to the concentration of lithium in the sample.

Substantial Equivalence:

The Multigent Lithium assay is substantially equivalent to the Infinity Lithium Liquid Stable Reagent assay (K003583) on the Hitachi 911 Analyzer. These assays yield similar Performance Characteristics.

Similarities:

- Both assays are in vitro clinical chemistry methods.
- Both assays can be used for the quantitative determination of lithium in serum or plasma.
- Both assays yield similar clinical results.
- Both assays claim similar assay ranges.

Differences:

None.

Intended Use:

The Multigent Lithium assay is used for the quantitation of lithium in serum or plasma.

Performance Characteristics:

Comparative performance studies were conducted using the AEROSET and ARCHITECT c8000 Systems. The Multigent Lithium assay method comparison yielded acceptable correlation with Infinity Lithium Liquid Stable Reagent assay on the Hitachi 911 Analyzer. The AEROSET System showed a correlation coefficient of 0.999, slope of 1.013, and Y-intercept of –0.025 mmol/L when compared to Infinity Lithium on the Hitachi 911. The ARCHITECT c8000 System showed a correlation coefficient of 0.999, slope of 0.991, and Y-intercept of – 0.004 mmol/L when compared to Infinity Lithium on the Hitachi 911. Precision studies were conducted using the Multigent Lithium assay. On the AEROSET System the total %CV for Level 1 is 4.76%, Level 2 is 3.67%, and Level 3 is 2.96%. On the ARCHITECT c8000 System the total %CV for Level 1 is 2.53%, Level 2 is 1.88%, and Level 3 is 2.02%. The Multigent Lithium assay is linear up to 3.51 mmol/L. The limit of quantititation (sensitivity) of the Multigent Lithium assay is 0.10 mmol/L. These data demonstrate that the performance of the Sentinel Lithium assay is substantially equivalent to the performance of the Infinity Lithium Liquid Stable Reagent assay on the Hitachi 911 Analyzer.

Conclusion:

The Multigent Lithium is substantially equivalent to the Infinity Lithium Liquid Stable Reagent assay on the Hitachi 911 Analyzer 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

Sentinel CH. SpA
c/o Mr. Fabio Rota, Technical Director
Via Robert Koch, 2
20152 Milano
Italy

AUG - 2 2007

Re: k070987
Trade/Device Name: Multigent Lithium
Regulation Number: 21 CFR§862.3560
Regulation Name: Lithium Test System
Regulatory Class: Class II
Product Code: NDW
Dated: June 21, 2007
Received: June 25, 2007

Dear Mr. Rota:

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): k070987

Device Name: Multigent Lithium

Indications For Use:

A lithium test system is a device intended to measure lithium levels in serum or plasma. Measurements of lithium are used to aid in the management of individuals taking lithium for the treatment of mental disturbances, such as manic-depressive illness (bipolar disorder). For use on Architect and Aeroset analyzers.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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