K083601

510(k) Summary

JUN 22 2009

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Date of Preparation of this Summary:	June 17th, 2009
Device Trade or Proprietary Name:	Lambda light chains Assay
Classification Name:	Immunoglobulin (light chain specific) immunological test system.
Classification Number/Class:	Class II / 866.5550
Product Code:	DEH

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: **K083601**

Test Description:

The Lambda light chains assay is an *in vitro* diagnostic test used for the quantitative determination of Immunoglobulin bound and free Lambda light chains (LAMBDA) in serum and Li-heparin plasma by immunoturbidimetry. It is intended to measure Immunoglobulin Lambda light chains (bound and free) using Synchron LX20 System. Measurement of various amounts of the different types of light chains aids in the diagnosis of multiple myeloma, lymphocytic neoplasms (cancer of lymphoid tissue), Waldenstrom's macroglobulinemia (increased production of large immunoglobulins) and connective tissue diseases such as rheumatoid arthritis or systemic lupus erythematosus in conjunction with other clinical and laboratory findings.

The determination of Lambda light chains is based on the specific turbidimetric reaction, which occurs between a polyclonal antiserum against human Immunoglobulin Lambda light chains and its corresponding antigen under optimal pH conditions and in the presence of polyethylene glycol (PEG). The turbidity of the immune complex is proportional to the concentration of the analyte in the sample.

Substantial Equivalence:

The Lambda light chains assay is substantially equivalent to Beckman IMMAGE Immunochemistry System Lambda light chain (K964260) on the IMMAGE nephelometer Analyzer. Both assays yield similar Performance Characteristics.

Similarities:

- Both assays are used for the quantitative determination of Lambda light chains (free and bound).
- Both assays are based on immunologic reaction between the Lambda light chains of human immunoglobulin and a specific polyclonal.
- Both assay detect bound and free Lambda light chains
- Both assays utilize reagents in R1 and R2 format.
- Both assays are traceable to ERM-DA 470 (European Reference Material) from BCR (EG Community Bureau of Reference), corresponding to RPPHS (Reference Preparation for Protein in Human Serum).
- Both assays yield similar clinical results.

Differences:

- The predicate device assay uses serum only as specimens. Sentinel assay uses serum and Li-Heparin plasma.
- The predicate device quantificates Lambda light chains by nephelometry. Sentinel assay quantificates Lambda light chains by immunoturbidimetry.
- In the predicate device, values are given in mg/dL and expressed as "equivalent weight of the intact immunoglobulin molecules (IgG + IgA + IgM = Kappa + Lambda). Thus the Molecular Weight of the Light chains is considered to be 150000 dalton (as the MW of whole IgG).
- In the Sentinel assay, values are given in mg/dL and expressed as content of Immunoglobulin light chains. The Molecular Weight of the Light chains is estimated to be 25000 dalton. Therefore, the results on Beckman Immage are about 3 times higher than results on Synchron LX.

Intended Use:

The Lambda light chains assay is an *in vitro* diagnostic test used for the quantitative determination of Immunoglobulin bound and free Lambda light chains (LAMBDA) in serum and Li-heparin plasma by immunoturbidimetry. It is intended to measure Immunoglobulin Lambda light chains (bound and free) using Synchron LX20 System. Measurement of various amounts of the different types of light chains aids in the diagnosis of multiple myeloma, lymphocytic neoplasms (cancer of lymphoid tissue), Waldenstrom's macroglobulinemia (increased production of large immunoglobulins) and connective tissue diseases such as rheumatoid arthritis or systemic lupus erythematosus in conjunction with other clinical and laboratory findings.

Performance Characteristics:

Comparative performance studies were conducted using the Synchron LX20 System. Sentinel Lambda light chains on Synchron LX20 System method comparison yielded acceptable correlation with the Beckman Lambda light chain (K964260) on IMMAGE nephelometer Analyzer.

Method comparison:

Lambda light chains assay on Synchron LX20 System was calibrated with a calibrator material with assigned Lambda Light chains concentration based on definition of Lambda Light chains as Whole IgG content (MW 150000).

This comparison showed a correlation coefficient (r) of 0.981, slope of 0.928 and Y-intercept of 58.59 mg/dL.

Conclusion:

Data generated demonstrated an acceptable correlation between the Lambda Light chains assay on the Synchron LX20 System vs. the IMMAGE Immunochemistry System Lambda light chains (K964260) on IMMAGE nephelometer Analyzer.

Precision:

Precision studies were conducted using Lambda light chains on the Synchron LX20 System. The found %CV values for 20x2x2 test (day x run x rep) on 5 levels (N=80 for each level) were:

	Total Imprecision		Between days		Within run	
Mean (mg/dL)	SD (mg/dL)	CV%	SD (mg/dL)	CV%	SD (mg/dL)	CV%
67.7	3.19	4.7	1.78	2.6	2.35	3.5
243.6	7.05	2.9	6.04	2.5	3.64	1.5
168.7	5.77	3.4	4.62	2.7	2.68	1.6
387.0	16.56	4.3	11.94	3.1	4.27	1.1
415.9	17.89	4.3	14.08	3.4	6.19	1.5

Analytical Measurement Range (AMR):

The found lower limit of the AMR of Lambda light chains on the Synchron LX20 System was 20mg/dL. The found upper limit of the AMR was 423 mg/dL. The claimed AMR will be 20 to 400 mg/dL.

Conclusion for 510(k) Summary:

These method comparison, precision and AMR data demonstrate that the analytical performance of the Lambda light chains on the Synchron LX20 System is substantially equivalent to IMMAGE Immunochemistry System Lambda light chain (K964260) on the IM MAGE nephelometer Analyzer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 22 2009

SENTINEL CH SpA
c/o Dr. Yangtse Portelles
Regulatory Affairs
Via Robert Koch, 2
20152 Milan
Italy

Re: k083601
Trade/Device Name: Lambda Light Chains Assay
Regulation Number: 21 CFR §866.5550
Regulation Name: Immunoglobulin (light chain specific) immunological test
Regulatory Class: Class II
Product Code: DEH
Dated: June 5th, 2009
Received: June 10th, 2009

Dear Dr. Portelles:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083601

Device Name: Lambda light chains

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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)

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Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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