SEP 1 0 2008

510 (k) Summary for the Dimension® clinical chemistry system Enzyme I Calibrator (DC35)

510 (k) Number: K081789

Analyte: Lactate dehydrogenase

Type of Test: Calibrator Material

Applicant:

Siemens Healthcare Diagnostics Inc
P.O. Box 6101
Newark, DE 19714-6101
Helen M. Lee
Regulatory Affairs and Compliance Manager
Office Phone: 302.631.8706
Fax: 302.631.6299

Proprietary and Established Name:

Dimension® clinical chemistry system Enzyme I Calibrator

Regulatory Information:

Regulation Section: 21 CFR § 862.1150 - Calibrator

Classification: Class II

Product Code: JIT – Calibrator, Secondary

Panel: Clinical Chemistry

Intended Use:

The ENZ I CAL is an *in vitro* diagnostic product for the calibration of the LDI method on the Dimension® clinical chemistry system.

Device Description:

ENZ I CAL is a liquid, bovine serum albumin based product containing lactate dehydrogenase (chicken heart). The calibrator packaging contains 4 vials, 2 vials of Level 2 and two vials of Level 3, with 1.5 mL per vial. Level 1 calibrator for LDI is not included in the ENZ I CAL carton. Purified Water Diluent (Cat. No. 710615901) or reagent grade water is required for use as Calibrator Level 1 for the LDI method.

Substantial Equivalence Information:

Comparison of the Dimension® clinical chemistry system Enzyme I Calibrator, proposed device, to the predicate Roche Calibrator for automated systems.

Item	New Device	Predicate Device
Analyte	Lactate dehydrogenase.	Multi-analyte; including lactate dehydrogenase.
Use	For the calibration of the lactate dehydrogenase (LDI) method on the Dimension® clinical chemistry system. For *in vitro* diagnostic use.	For use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheet. For *in vitro* diagnostic use.
Matrix	Liquid bovine serum albumin base with lactate dehydrogenase of chicken liver origin.	Human serum base with lactate dehydrogenase of porcine heart origin.
Form	Liquid	Lyophilized
Traceability	IFCC *LD* at *37* ° C primary reference method.	Standardized against the original formulation and procedures recommended by the IFCC.

Comments on Substantial Equivalence:

Both the proposed ® clinical chemistry system Enzyme I Calibrator and the predicate Roche Calibrator for automated systems are traceable to IFCC reference method and used to calibrate IFCC traceable lactate dehydrogenase methods.

Conclusion:

The Dimension® Enzyme I Calibrator is substantially equivalent to the Roche Calibrator for automated systems based upon the information above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Siemens Healthcare Diagnostics Inc.
c/o Ms. Helen M. Lee
500 GBC Drive
P.O. Box 6101, Mailbox 514
Newark, DE 19714-6101

SEP 1 0 2008

Re: k081789
Trade/Device Name: Dimension® Chemistry System Enzyme I Calibrator (ENZ I Cal)
Regulation Number: 21 CFR§ 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: June 24, 2008
Received: June 25, 2008

Dear Ms. Lee:

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 Statement

510(k) Number (if known): K081789

Device Name:

Dimension® clinical chemistry system Enzyme I Calibrator (ENZ I CAL)

Indications for Use:
The ENZ I CAL is an *in vitro* diagnostic product for the calibration of LDI method on the Dimension® clinical chemistry system.

Prescription Use ___X___ (Per 21 CFR 801 Subpart D)

Over-The-Counter-Use_____ (21 CFR 801)

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

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

Carol C. Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K081789