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FEB 16 2011

510(k) Summary for Dimension ® ENZ II CAL

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: K103836

1. **Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:**

Manufacturer: Siemens Healthcare Diagnostics, Inc.
500 GBC Drive
Newark, DE 19714

Contact Information: Siemens Healthcare Diagnostics, Inc.
500 GBC Drive
Newark, DE 19714
Attn: A. Kathleen Ennis
Tel: 302-631-9352
Fax: 302-631-6299

Preparation date: November 15, 2010

2. **Device Name:** ENZ II CAL

Classification: Class II

Product Code: JIX;

Panel: Clinical Chemistry (75)

3. **Identification of the Legally Marketed Device:**

Dimension Vista® ENZ 2 CAL k061390

4. **Device Descriptions:**

ENZ II CAL is a liquid, multi-analyte, bovine serum albumin based product containing alanine aminotransferase from porcine heart.

5. **Device Intended Uses:**

Dimension Vista ® ENZ 2CAL

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The ENZ II CAL is an *in vitro* diagnostic product for the calibration of the alanine aminotransferase (ALT I) method on the Dimension® clinical chemistry system.

6. **Medical device to which equivalence is claimed and comparison information:**
The Dimension® ENZ II CAL, modified, is substantially equivalent to the Dimension Vista® ENZ 2 CAL. ENZ II CAL like the predicate, is an *in vitro* diagnostic product intended to be used for the calibration of the alanine aminotransferase assay.

7. **Comparative Features Table**

Feature	Predicate Device Dimension Vista® ENZ 2 Calibrator	New Device Dimension® ENZ II Calibrator
Similarities		
Intended Use:	ENZ 2 CAL is an *in vitro* diagnostic product for calibration of automated clinical chemistry analyzers.	ENZ II CAL is an *in vitro* diagnostic product for calibration of automated clinical chemistry analyzers
Form:	liquid, bovine serum albumin based	liquid, bovine serum albumin based
Packaging:	ENZ 2 CAL is packaged in plastic vials containing 1.5 mL/vial. Each carton contains 2 vials of each level.	ENZ II CAL is packaged in plastic vials containing 1.5 mL/vial. Each carton contains 2 vials of each level.
Stability and storage	ENZ 2 CAL is stored at 2 to 8° C	ENZ II CAL is stored at 2 to 8° C
Differences		
Intended Use:	ENZ 2 CAL is an *in vitro* diagnostic product for calibration of the Aspartate Aminotransferase (AST) and Alanine Aminotransferase (ALT) methods on the Dimension Vista® System.	ENZ II CAL is an *in vitro* diagnostic product for calibration of the Alanine Aminotransferase (ALTI) method on the Dimension ® clinical chemistry system.
Assigned Constituents:	aspartate aminotransferase and alanine aminotransferase from porcine heart	alanine aminotransferase from porcine heart
Traceability of constituents:	ALT and AST traceable to Master pool, Dimension® clinical chemistry system values	ALT I traceable to the IFCC ALT@ 37°C primary reference method.
Levels:	2 levels Level 1 - 0 U/L Level 2 – 1047 U/L	3 levels Level 1 - 0 U/L Level 2 - 550 U/L Level 3 – 1100 U/L

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8. Conclusion

Dimension ENZ II CAL is substantially equivalent in intended use to the legally marketed device, Dimension Vista® ENZ 2 Calibrator based on the information described above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

FEB 16 2011

Siemens Healthcare Diagnostics, Inc.
c/o Anna Marie Kathleen Ennis, Regulatory Affairs Manager
500 GBC Drive
PO Box 6101
Newark, DE 19714-6101, USA

Re: k103836
Trade Name: Siemens Dimension® ENZ II Calibrator
Regulation Number: 21 CFR §862.1150
Regulation Name: Calibrators
Regulatory Class: Class II
Product Codes: JIT
Dated: February 9, 2011
Received: February 10, 2011

Dear Ms. Ennis:

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).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
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 Form

510(k) Number (if known): K103836

Device Name: Dimension® ENZ II CAL

Indications for Use:

The Enzyme II Calibrator is an *in vitro* diagnostic product for the calibration of Alanine Aminotransferase (ALTI) on the Dimension® clinical chemistry system.

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

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

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

Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

510(k) K103836