FEB 20 2009

510(k) Summary of Safety and Effectiveness for the Dimension Vista® System Enzyme 6 Calibrator (KC360)

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.

A. 510(k) Number: K083579

B. Date of Preparation: November 24, 2008

C. Proprietary and Established Names:
Enzyme 6 Calibrator

D. Applicant:
Siemens Healthcare Diagnostics Inc., P.O. Box 6101, Newark, DE 19714-6101
Victor M. Carrio, Senior Manager, Regulatory Affairs
Office: (302) 631-0376 Fax: (302) 631-6299

E. Regulatory Information:
Regulation section: 21 CFR § 862.1150 Calibrator
Classification: Class II
Product Code: JIX, Calibrator, Multi-Analyte Mixture
Panel: Clinical Chemistry

F. Predicate Devices:
Dimension® CKI/MBI Calibrator (K081731)

G. Device Description:
The Dimension Vista® System Enzyme 6 Calibrator (Enz 6 CAL) is a liquid, multi-analyte, human serum albumin based product containing creatine kinase MM (human source) and creatine kinase MB (porcine source). The kit consists of three vials of Calibrator A, 2.0 ml per vial. Level 1 calibrator for Enz 6 CAL is not included. Purified Water Diluent or reagent grade water is required for use as Calibrator Level 1. Description of the manufacturing, value assignment and stability testing process are provided in this submission report.

H. Intended Use:
The ENZ 6 CAL is an in vitro diagnostic product for the calibration of the Creatine Kinase (CKI) and Creatine Kinase MB (MBI) methods on the Dimension Vista® System.

I. Substantial Equivalence Information:
The Dimension Vista® Enzyme 6 Calibrator (KC360) was compared to the Dimension® CKI/MBI Calibrator (K081731). A comparison of the important similarities and differences between the device and the predicate is provided in the following table:

Feature	Dimension Vista® Enzyme 6 Calibrator	Dimension® CKI/MBI Calibrator (K081731)
Intended Use	The ENZ 6 CAL is an in vitro diagnostic product for the calibration of the Creatine	The CKI/MBI CAL is an *in vitro* diagnostic product for the calibration of the Creatine

	Kinase (CKI) and Creatine Kinase MB (MBI) methods on the Dimension Vista® System.	Kinase (CKI) and Creatine Kinase MB (MBI) methods on the Dimension® clinical chemistry system.
Analyte	Creatine kinase (human source) and creatine kinase-MB (porcine source)	Creatine kinase (human source) and creatine kinase-MB (porcine source)
Matrix	Human serum albumin	Human serum albumin
Form	Liquid	Liquid
Levels	CKI – Two levels MBI – Two levels	CKI - Three levels MBI – Five levels

J. Conclusion:

The Dimension Vista® Enzyme 6 Calibrator (KC360) is substantially equivalent to the Dimension® CKI/MBI Calibrator (K081731). Comparative testing described in the protocol included in this submission demonstrates substantial equivalent performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Siemens Healthcare Diagnostics Inc.
c/o Mr. Victor M. Carrio
Senior Manager Regulatory Affairs
P.O. Box 6101
Newark, DE 19714-6101

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Re: k083579
Trade/Device Name: Dimension Vista® Enzyme 6 Calibrator
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator, Multi-Analyte
Regulatory Class: Class II
Product Code: JIX
Dated: December 3, 2008
Received: December 4, 2008

Dear Mr. Carrio:

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 (301) 594-3084. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known): K083579

Device Name:

Dimension Vista® Enzyme 6 Calibrator

Indication For Use:

The ENZ 6 CAL is an in vitro diagnostic product for the calibration of the Creatine Kinase (CKI) and Creatine Kinase MB (MBI) methods on the Dimension Vista® System.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K083579