AUG 22 2008

510(k) Summary of Safety and Effectiveness
Dimension Vista® Cyclosporine Extended Range Calibrator

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: k082030

1. Submitter's Contact Information and Date of Preparation

Contact Information:	Siemens Healthcare Diagnostics Inc. P.O. Box 6101 Newark, DE 19714-6101 Attn: Yuk-Ting Lewis Tel: 302-631-7626
Date of Preparation:	July 10, 2008

2. Proprietary Device Name / FDA Classification Name

Dimension Vista® Cyclosporine Extended Range Calibrator / Clinical Toxicology Calibrator

3. Identification of the Predicate Device

Dimension® CSAE Cyclosporine Extended Range Calibrator, K061503

4. Device Description

The Dimension Vista® Cyclosporine Extended Range Calibrator contains cyclosporine in a preserved whole blood hemolysate. The kit consists of three vials of Calibrator A (200 ng/mL) and three vials of Calibrator B (2000 ng/mL). The intermediate calibrator levels (400, 800 and 1400 ng/mL) are prepared on-board the Dimension® Vista analyzer.

5. Device Intended Use

The CSAE CAL is an in vitro diagnostic product for the calibration of CSAE method on the Dimension Vista® system.

6. Summary of the devices technological characteristics

A comparison of the Dimension Vista® CSAE Calibrator vs. the predicate device is provided.

Characteristic	(New Device) **Dimension Vista® Cyclosporine Extended Range Calibrator**	(Predicate) **Dimension® CSAE Cyclosporine Extended Range Calibrator, K061503**
Intended Use	The CSAE CAL is an in vitro diagnostic product for the calibration of CSAE method on the Dimension Vista® system.	The Dimension® CSAE Cyclosporine Extended Range Calibrator is an in vitro diagnostic product intended to be used to calibrate the CSAE Cyclosporine Extended range method for the Dimension® clinical chemistry system or the Syva® Emit® 2000 Cyclosporine Specific Assay.
Analyte	Cyclosporine	
Matrix	Preserved whole blood hemolysate	
Number of levels and target concentrations	Two levels: 200 and 2000 ng/mL cyclosporine. The intermediate calibrator levels (400, 800 and 1400 ng/mL) are prepared on-board the Dimension® Vista analyzer.	Five levels: 200, 400, 800, 1400 and 2000 ng/mL cyclosporine.
Stability	The stability of the calibrators is established through real-time data on 3 lots of product. Testing is conducted at multiple time points and must pass pre-defined acceptance criteria.	
Traceability	The calibrator is traceable to an internal master pool containing USP cyclosporine A and whose values are confirmed by LC/MS/MS.	

7. Conclusion

Based on a review of the devices technological features, the Dimension Vista® Cyclosporine Extended Range Calibrator is substantially equivalent to the legally marketed device, the Dimension® CSAE Cyclosporine Extended Range Calibrator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 22 2008

Siemens Healthcare Diagnostics, Inc.
c/o Yuk-Ting Lewis
Regulatory Affairs & Compliance Manager
P.O. Box 6101, Mail Stop 514
Newark, DE 19714-6101

Re: k082030
Trade Name: Dimension Vista® Cyclosporine Extended Range Calibrator
Regulation Number: 21 CFR 862.3200
Regulation Name: Clinical Toxicology Calibrator.
Regulatory Class: Class II
Product Codes: DLJ
Dated: July 15, 2008
Received: July 17, 2008

Dear Ms. Lewis:

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

Indication for Use

510(k) Number (if known): K082030

Device Name: Dimension Vista® Cyclosporine Extended Range Calibrator

Indications For Use:

The CSAE CAL is an in vitro diagnostic product for the calibration of CSAE method 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

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