SEP 1 1 2008

510(k) Summary
ADVIA Centaur® Cyclosporine Assay

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: K071455

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

Submitter: Siemens Healthcare Diagnostics
511 Benedict Avenue
Tarrytown, New York 10591-5097

Contact Information: Mary Seeger, Ph.D.
Phone: 914-524-2908
Fax : 914-524-2500

Date of Preparation: August 19, 2008

2. Device Name / Classification

Common Name: Cyclosporine
Trade Name: ADVIA Centaur® Cyclosporine Assay
ADVIA Centaur® Cyclosporine Calibrator
FDA Classification: Sec. 862.1235, 862.3200
Cyclosporine Test system – Class II Special controls
Clinical Toxicology Calibrator

3. Identification of the Predicate Devices

Abbott TDx®/TDxFLx® Cyclosporine Monoclonal Whole Blood assay, P890025

4. Device Description

The ADVIA Centaur® Cyclosporine assay is a competitive immunoassay using direct chemiluminescent technology. Cyclosporine in the patient sample competes with acridinium ester-labeled cyclosporine in the Lite Reagent for a limited amount of biotin-labeled monoclonal mouse anti-cyclosporine antibody. Biotin-labeled anti-cyclosporine binds to streptavidin that is covalently coupled to paramagnetic particles in the

Solid Phase. In the ADVIA Centaur® Cyclosporine assay the sample is manually pretreated to lyse the cells and solubilize the cyclosporine.
An inverse relationship exists between the amount of cyclosporine present in the patient sample and the amount of relative light units (RLUs) detected by the system.

5. Device Intended Use

The ADVIA Centaur® Cyclosporine assay is an *in vitro* diagnostic immunoassay for the quantitative determination of cyclosporine in human whole blood using the ADVIA Centaur systems. This assay is intended for use as an aid in the management of cyclosporine therapy in kidney, heart, and liver transplant patients.

The ADVIA Centaur® Cyclosporine Calibrator is for *in vitro* diagnostic use in the calibration of the Cyclosporine assay on the ADVIA Centaur® system.

6. Comparison to Predicate Devices

The ADVIA Centaur® Cyclosporine assay is substantially equivalent to Abbott TDx®/TDxFLx® Cyclosporine Monoclonal Whole Blood assay in that:

- Both are immunoassays intended for use in the quantitative measurement of cyclosporine in human whole blood.
- Both assays use mouse monoclonal antibody
- Both assays require pretreatment of patient samples.

The ADVIA Centaur® Cyclosporine assay and Abbott TDx®/TDxFLx® Cyclosporine Monoclonal Whole Blood assay differ in that:

- The ADVIA Centaur® Cyclosporine assay does not require whole blood precipitation reagent before testing.
- The ADVIA Centaur® Cyclosporine assay does not require pretreatment of calibrators.

Comparison Information

Method comparison studies were conducted at three external sites comparing the ADVIA Centaur® Cyclosporine assay against two predicates:

- Tandem Mass Spectrometry, and
- The Abbott TDx®/TDxFLx® Cyclosporine Monoclonal Whole Blood assay.

Samples from three transplant patient groups (heart, kidney and liver) were used in the studies. The data from all three sites were analyzed by Deming regression.

Comparative Method	Transplant Type	Number of Patient Samples	Slope	Intercept	Correlation Coefficient
Tandem-MS	kidney	108	1.11	-8	0.962
	liver	75	1.04	-5	0.967
	heart	67	0.89	20	0.966
	all	250	1.03	-1	0.963

Comparative Method	Site	Number of Patient Samples	Slope	Intercept	Correlation Coefficient
Tandem-MS	site 1	97	0.88	13	0.979
	site 2	105	0.85	23	0.988
	site 3	48	1.11	46	0.965
	all	250	0.94	19	0.960
Abbott TDx	site 1	97	0.78	8	0.977
	site 2	97	0.68	-3	0.988
	site 3	48	0.71	22	0.977
	all	242	0.72	6	0.977
Abbott AxSym	site 1	219	0.68	18	0.960

Comparative Method	Site	Number of Patient Samples	Slope	Intercept	Correlation Coefficient
Tandem-MS	trough	182	1.02	8	0.909
	peak	68	1.15	-104	0.898
	all	250	1.03	-1	0.963

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Siemens Medical Solutions Diagnostics
c/o Dr. Mary Seeger
Manager Regulatory Affairs
511 Benedict Avenue
Tarrytown, NY 10591

Re: k071455
Trade/Device Name: Advia Centaur® Cyclosporine Assay and
Advia Centaur® Cyclosporine Calibrator
Regulation Number: 21 CFR 862.1235
Regulation Name: Cyclosporine Test System.
Regulatory Class: Class II
Product Code: MKW, DLJ
Dated: September 3, 2008
Received: September 4, 2008

Dear Dr. Seeger:

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): K071455

Device Name: ADVIA Centaur Cyclosporine Assay and Calibrators

Indication For Use: The ADVIA Centaur Cyclosporine assay is an *in vitro* diagnostic immunoassay for the quantitative determination of cyclosporine in human whole blood using the ADVIA Centaur systems. This assay is intended for use as an aid in the management of cyclosporine therapy in kidney, heart, and liver transplant patients.

Prescription Use X And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (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) K071455