510(k) Summary of Safety and Effectiveness for the

ADVIA® Chemistry DRUG Calibrator I

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: K093732

B. Date of Preparation: December 03, 2009

C. Proprietary and Established Names:

MAR 22 2010

ADVIA® Chemistry DRUG Calibrator I

D. Applicant:

Siemens Healthcare Diagnostics Inc., 511 Benedict Ave, Tarrytown, NY 10591

Kira Gordon, Sr. Regulatory Affairs Specialist

Office: (914) 524-2996 Fax: (914) 524-2500

E. Regulatory Information:

ADVIA Chemistry DRUG Calibrator I

1. Regulation section: 21 CFR § 862.1150 Calibrator.

2. Classification: Class II

3. Product Code: JIX, calibrator, multi-analyte mixture

4. Panel: Clinical Chemistry

F. Predicate Device:

ADVIA Chemistry DRUG Calibrator I is substantially equivalent to the (formerly) Dade Behring Dimension Drug Calibrator (DC22B) cleared under K011035.

G. Device Description:

ADVIA Chemistry DRUG Calibrator I is a multi-analyte, liquid, human serum based product containing multiple analytes. The kit consists of 2 vials each of 5 calibrator levels which are ready for use (no preparation is required). The volume per vial is 3.0 mL. Phenobarbital, Phenytoin, and Theophylline are value assigned for ADVIA

Chemistry systems. In addition DRUG Calibrator I also contains Lithium and Digoxin with no specific value assignment on ADVIA Chemistry systems at this time.

H. Intended Use:

The ADVIA Chemistry DRUG Calibrator I is for *in vitro* diagnostic use in the calibration of Phenobarbital (PHNB_2), Phenytoin (PHNY_2), and Theophylline (THEO_2) methods on the ADVIA Chemistry Systems

I. Substantial Equivalence Information:

The ADVIA Chemistry DRUG Calibrator I and Dimension Drug Calibrator I were compared in the following table.

Item	**New Device** - The ADVIA Chemistry DRUG Calibrator I	**Predicate Device** - (formerly) Dade Behring Dimension Drug Calibrator (DC22B)
Intended Use	for *in vitro* diagnostic use in the calibration of Phenobarbital_2 (PHNB_2), Phenytoin_2 (PHNY_2), and Theophylline_2 (THEO_2) methods on the ADVIA Chemistry Systems .	DRUG CAL is an *in vitro* diagnostic product intended to be used to calibrate digoxin, lithium, phenobarbital, phenytoin and theophylline methods on the Dimension System
Formulation / analytes present	Digoxin Phenobarbital Phenytoin Theophylline Lithium	Digoxin Phenobarbital Phenytoin Theophylline Lithium
Measured Analytes (value assigned)	Phenobarbital Phenytoin Theophylline	Digoxin Phenobarbital Phenytoin Theophylline Lithium
Form	Liquid	Liquid
Traceability	USP	USP
Matrix	Human Serum	Human Serum
Number of Levels	five	five
Packaging	Ten vials: two vials at five levels (3.0 mL each)	Ten vials: two vials at five levels (3.0 mL each)
Stability	18 months – shelf-life 90 days open vial	18 months – shelf-life 90 days open vial

J. Conclusion:

The multi-analyte, five level, human serum based ADVIA Chemistry DRUG Calibrator I is substantially equivalent to the Dimension DRUG Calibrator. They are identical in composition and both used in calibration of TDM methods on Chemistry systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Siemens Healthcare Diagnostics
c/o Kira Gordon
511 Benedict Ave
Tarrytown, NY 10591

MAR 22 2010

Re: k093732
Trade Name: Advia Chemistry Drug Calibrator I
Regulation Number: 21 CFR §862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Codes: JIX
Dated: February 5, 2010
Received: February 12, 2010

Dear Ms. Gordon:

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 Part 801), 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. 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

510(k) Number (if known): K093732

Device Name: ADVIA® Chemistry DRUG Calibrator I

Indications For Use:

For *in vitro* diagnostic use in the calibration of Phenobarbital_2 (PHNB_2), Phenytoin_2 (PHNY_2), and Theophylline_2 (THEO_2) methods on the ADVIA Chemistry Systems .

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)

Carol C Benson

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

K093732