k083386

510(k) Summary of Safety and Effectiveness for the

ADVIA® Chemistry Calcium_2 Method

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: k083386

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B. Date of Preparation: September 29, 2008

C. Proprietary and Established Names:

ADVIA® Chemistry Calcium_2 Method

D. Applicant:

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

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Office (914) 524-2531 Fax: (914) 524-2500

E. Regulatory Information:

ADVIA Chemistry Calcium_2 Method

1. Regulation section: 21 CFR § 862.1145 Calcium test system.

2. Classification: Class II

3. Product Code: CJY, azo dye, calcium

4. Panel: Clinical Chemistry

F. Predicate Device:

ADVIA Chemistry Calcium_2 Method is substantially equivalent to the ADVIA Chemistry 1650 Calcium method cleared under K991576.

G. Device Description:

Summary and Explanation: the Calcium_2 (CA_2) method is based on the work of Michaylova and Illkova, (Anal Chem Acta 1971; 53: 194), who found that Arsenazo III could form a stable complex with calcium with high selectivity at low pH.

Principles of the Procedure: Calcium ions form a colored complex with Arsenazo III, which is measured at 658/694 nm. The amount of calcium present in the sample is directly proportional to the intensity of the colored complex formed.

Reaction Equation: Ca^{2+} + *Arsenazo III ---> Ca-Arsenazo III Complex (purple)*

H. Intended Use:

For *in vitro* diagnostic use in the quantitative determination of calcium in human serum, plasma, and urine on the ADVIA Chemistry systems. Such measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal failure, and tetany

I. Substantial Equivalence Information:

The ADVIA Chemistry Calcium_2 Method and ADVIA 1650 Calcium methods were compared. A comparison of the important similarities and differences between the device and the predicate is provided in the following tables:

Similarities		
Characteristics	Siemens ADVIA Calcium_2(new device)	Bayer (currently Siemens) ADVIA 1650 Calcium (predicate device)
Intended Use	same	same
Sample Type	Serum, plasma (Li-heparin) and urine	Serum, plasma (Li-heparin) and urine
Instrument	ADVIA® Chemistry systems	ADVIA® Chemistry systems
Calibrators	Siemens Chemistry Calibrator (K030169)	Same (K030169)
Controls used	BioRad controls	BioRad controls
Method	colorimetry	colorimetry

Differences		
Characteristics	Siemens ADVIA Calcium_2(new device)	Bayer (currently Siemens) ADVIA 1650 Calcium (predicate device)
Assay Protocol	Calcium ions form a colored complex with Arsenazo III, which is measured at 658/694 nm. The amount of calcium present in the sample is directly proportional to the intensity of the colored complex formed. ***Reaction Equation***: *Ca^{2+} + Arsenazo III -> Ca-Arsenazo III Complex (purple)*	Calcium ions form a violet complex with *o*-cresolphthalein complexone in an alkaline medium. The reaction is measured at 545/658 nm. ***Reaction Equation***: *CPC + $2Ca^{2+}$ ->CPC $(Ca2+)_2$ Complex*

Reagents	One liquid reagent	Two liquid reagents
Expected Values	Serum/Plasma: 8.7-10.4 mg/dL (2.18-2.60 mmol/L) Urine: 100-300 mg/day (2.5-7.5 mmol/day)	Serum/Plasma: 8.3-10.6 mg/dL (2.08-2.65 mmol/L) Urine: 100-300 mg/day (2.5-7.5 mmol/day)
Measuring Range	Serum/Plasma: 1.0 – 16.0 mg/dL (0.25 – 4.0 mmol/L) Urine 1.0 – 32 mg/dL (0.25 – 8.0 mmol/L)	Serum/ Plasma: 1.0 – 15.0 mg/dL (0.25 – 3.75 mmol/L) Urine: 1.0 – 30.0 mg/dL (0.25 – 7.50 mmol/L)

J. Conclusion:

The ADVIA Chemistry Calcium_2 Method is substantially equivalent to the ADVIA 1650 Calcium method cleared under K991576. Comparative testing described in the protocol included in this submission demonstrates substantially equivalent performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Siemens Healthcare Diagnostics
c/o Philip Liu, Ph.D.
Manager, Regulatory Affairs and Compliance
511 Benedict Ave.
Tarrytown, NY 10591

Re: k083386
Trade Name: ADVIA Chemistry Calcium_2 Method
Regulation Number: 21 CFR 862.1145
Regulation Name: Calcium test system
Regulatory Class: Class II
Product Codes: CJY
Dated: February 27, 2009
Received: March 4, 2009

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Dear Dr. Liu:

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): k083386

Device Name: ADVIA® Chemistry Calcium_2 Method

Indication For Use:

For *in vitro* diagnostic use in the quantitative determination of calcium in human serum, plasma, and urine on the ADVIA Chemistry systems. Such measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal failure, and tetany.

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)

Carol C Benson

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

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