510(k) Summary of Safety and Effectiveness
ADVIA Centaur® with StreamLAB® Analytical Workcell

FEB 2 6 2009

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: K082638

1. Submitter's Contact Information and Date of Preparation

Submitter's Contact Information:

Siemens Healthcare Diagnostics Inc.
P.O. Box 6101
Newark, DE 19714-6601
Attn: Yuk-Ting Lewis
Tel: 302-631-7626

Date of Preparation: February 25, 2009

2. Proprietary Device Name / FDA Classification Name

ADVIA Centaur® with StreamLAB® Analytical Workcell / Class I: Discrete photometric chemistry analyzer for clinical use (21CFR§862.2160), Product Code JJE

3. Identification of the Predicate Device

Predicate Instrument or Method	510(k)	Product Code
ADVIA Centaur®	K041133	JJE
StreamLAB® Analytical Workcell	K043546	JJE
ADVIA Centaur® T4 Assay	K905532	CDX

4. **Device Description(s):**

The ADVIA Centaur® is a continuous operation, immunochemistry analyzer designed to perform in vitro diagnostic testing on clinical specimens.

The StreamLAB® Analytical Workcell is a laboratory automation system (LAS) designed to automate sample handling and processing in the clinical laboratory.

The ADVIA Centaur® with StreamLAB® Analytical Workcell combines the features of both the analyzer and the laboratory automation system.

The StreamLAB routes samples to the Centaur analyzer based on test request information it (StreamLAB) receives from the Laboratory Information System (LIS) and the test map established for the Centaur analyzer. StreamLAB and Centaur communicate sample and analyzer status via Centaur's Laboratory Automation System (LAS) interface. Via its LIS interface, the Centaur analyzer interfaces separately with the hospital's LIS to receive its test instructions (test requests) and to report results for each sample. Centaur's test instructions and test results for each sample are not processed through the StreamLAB.

The StreamLAB performs the following pre and post-analytical functions.

- Sample bar code identification (previously performed by the Centaur)
- Sample transport and tracking
- Sample centrifugation (optional functionality)
- Sample de-capping (optional functionality)
- Sample transport and tracking
- Tube sealing (optional functionality)

The Centaur continues to perform the following functions, when connected to the StreamLAB.

- All functions except reading the sample tube bar code. When Centaur is connected to StreamLAB, samples can be loaded directly onto Centaur and/or loaded onto StreamLAB and routed to Centaur. For samples loaded onto StreamLAB, StreamLAB reads the sample tube bar code (sample identification) and passes it electronically to Centaur via the LAS interface to Centaur.

5. **Device Intended Use:**

The ADVIA Centaur with StreamLAB® Analytical Workcell is an automated immunoassay analyzer designed to perform in vitro diagnostic immunochemical assay analysis on clinical specimens. The system menu will include assays based on chemiluminescent technology, such as Thyroxine, along with other various chemiluminescent assays that may be adaptable to the analyzer depending on the reagent used to induce the chemiluminescent reaction.

The ADVIA Centaur T4 assay is for in vitro diagnostic use in the quantitative determination of thyroxine (T4) in serum on the ADVIA Centaur and ADVIA Centaur XP systems. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases.

6. **Medical device to which equivalence is claimed**

The ADVIA Centaur® with StreamLAB® Analytical Workcell is substantially equivalent to the ADVIA Centaur (K041133). The devices have same / similar design and modes of operation. The key features are summarized in the table.

Feature	**Predicate device: ADVIA Centaur® (K041133)**	**Proposed device: ADVIA Centaur® with StreamLAB® Analytical Workcell**
Intended Use	The ADVIA Centaur® is an automated immunoassay analyzer designed to perform in vitro diagnostic immunochemical assay analysis on clinical specimens. The system menu will include endocrine, anemia, allergy, reproductive, cardiovascular, oncology, adrenal, bone metabolism, therapeutic drug, and infectious disease assays. All assays are based on chemiluminescent technology.	The ADVIA Centaur with StreamLAB® Analytical Workcell is an automated immunoassay analyzer designed to perform in vitro diagnostic immunochemical assay analysis on clinical specimens. The system menu will include assays based on chemiluminescent technology, such as Thyroxine, along with other various chemiluminescent assays that may be adaptable to the analyzer depending on the reagent used to induce the chemiluminescent reaction.
Principles of Operation	Chemiluminescence using magnetic-particle solid phase and chemiluminescent label	
Optical System	Photomultiplier tube used in photon counting mode	
Sample Containers	Sample cups or primary tubes	Sample cups* or primary tubes
Sample Loading	Load directly onto the Centaur	Load directly onto the Centaur and/or load onto the StreamLAB
Sample Preparation	Manually centrifuged samples	Manually centrifuged samples or automatically centrifuged samples by the StreamLAB.

Feature	Predicate device: ADVIA Centaur® (K041133)	Proposed device: ADVIA Centaur® with StreamLAB® Analytical Workcell
	Manually decapped sample tubes	Manually decapped sample tubes or automatically decapped tubes by StreamLAB.
Sample Identification of Bar-coded Tubes	Tube bar code (identification) is read by the Centaur.	Tube bar code (identification) is read by the Centaur (when tubes are placed directly on the Centaur); or tube bar code read by StreamLAB and communicated electronically to the Centaur (when tubes are loaded onto StreamLAB).
Test Orders	Unidirectional communication with external LIS	
Test Results	Unidirectional communication with external LIS	
Laboratory Automation	Centaur's software communicates with Lab Automation System via LAS interface. Centaur performs direct sampling from tube on the track.	
* Sample cups cannot be used on the StreamLAB. Sample cups must be loaded directly onto the Centaur when connected to the StreamLAB. The StreamLAB does not impact Centaur's capability to accept sample cups.		

Method Comparison

Split-sample method comparison studies were conducted using the ADVIA Centaur® T4 Assay. Samples were processed either directly on the predicate device or on the proposed device. The data were analyzed by linear regression and the results are summarized in the table below.

Method	Slope	Intercept	r	Sy,x	n	Range
T4	1.050	-0.299	0.993	0.36	66	1.60 – 17.00 µg/dL

7. Conclusion:

The proposed ADVIA Centaur® with StreamLAB® Analytical Workcell and the predicate ADVIA Centaur® (K041133) are substantially equivalent in design, modes of operation, assay performance and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

FEB 2 6 2009

Re: k082638
Trade/Device Name: ADVIA Centaur with StreamLAB Analytical Workcell using Thyroxine reagents
Regulation Number: 21CFR Sec.862.1700.
Regulation Name: Total thyroxine test system
Regulatory Class: Class II
Product Code: KLI, JJE
Dated: February 20, 2009
Received: February 23, 2009

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 (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):

Device Name: ADVIA Centaur with StreamLAB® Analytical Workcell using Thyroxine reagents

Indications For Use:

The ADVIA Centaur with StreamLAB® Analytical Workcell is an automated immunoassay analyzer designed to perform in vitro diagnostic immunochemical assay analysis on clinical specimens. The system menu will include assays based on chemiluminescent technology, such as Thyroxine, along with other various chemiluminescent assays that may be adaptable to the analyzer depending on the reagent used to induce the chemiluminescent reaction.

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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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