K091123

510(k) Summary

Submitter information

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AUG 14 2009

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Date summary prepared: June 11, 2009

Device Trade or Proprietary Name: ADVIA® Centaur DHEAS Master Curve Material

Device Common/Usual Name or Classification Name: Single (Specified) Analyte Controls (Assayed And Unassayed)

Classification Number/Class: JJX / Class I

Classification Panel: Clinical Chemistry (75)

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

The assigned 510(k) number is: K091123

Predicate Devices:

Device Name	VALIDATE Thyroid Calibration Verification Test Set
Common name	VALIDATE THY Calibration Verification Test Set
510(k) Number	K062501
Manufacturer	Maine Standards Company

Device Description:

The ADVIA® Centaur DHEAS Master Curve Material are 5 levels of varying concentrations of DHEAS in delipidated, steroid stripped, human defribrinated plasma with preservative. The MCM Master Curve Materials have expected values (lot specific) of 0, 60, 300, 900 and 1500 ug/dL.

The MCM Master Curve Material (1.0 mL/vial) are liquid and ready to use. Storage is at 2 - 8°C.

CAUTION! POTENTIAL BIOHAZARD: Contains human source material. While each human serum or plasma donor unit used in the manufacture of this product was tested by FDA-approved methods and found nonreactive for hepatitis B surface antigen (HBsAg), antibody to hepatitis C (HCV), and antibody to HIV-1/2, all products manufactured using human source material should be handled as potentially infectious. Because no test method can offer complete assurance that hepatitis B or C viruses, HIV, or other infectious agents are absent, these products should be handled according to established good laboratory practices.

Statement of Intended Use:

The ADVIA® Centaur DHEAS Master Curve Material are for *in vitro* diagnostic use in the verification of calibration and reportable range in the ADVIA® Centaur Systems Dehydroepiandrosterone sulfate (DHEAS) assay.

Performance:

The traceability, value assignment, and stability of the ADVIA® Centaur DHEAS Master Curve Materials have been validated following procedures of Siemens Healthcare Diagnostics. These DHEAS Master Curve Material are substantially equivalent to currently marketed devices with similar intended uses.

Comparison to the Predicate Device:

Similarities and Differences between the devices and the predicate are shown below:

Comparison Table*

Item	Device ADVIA® DHEAS Master Curve Material	Predicate Maine Standards Company VALIDATE Thyroid Calibration Verification Test Set (K062501)
Intended Use	The ADVIA® Centaur DHEAS Master Curve Material are for *in vitro* diagnostic use in the verification of calibration and reportable range in the ADVIA Centaur® Systems Dehydroepiandrosterone sulfate (DHEAS) assay.	The VALIDATE Thyroid Calibration Verification Test Set solutions are for *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range in automated, semi-automated and manual chemistry systems.
Form	Liquid	Liquid
Analytes	DHEAS only	Multiple analytes including Triiodothyronine (Ta), Thyroxine ff4), human Thyroid Stimulating Hormone (TSH), and Cortisol
Storage	2°C to 8°C	-10°C to -20°C
Stability	**Unopened** – until expiration date on the vial label **Opened** – 60 days	**Unopened** – until expiration date on storage container when stored as directed
Differences	Verification of calibration and reportable range for the ADVIA Centaur® DHEAS assay.	Verification of calibration, linearity, and reportable range for multiple assays (Triiodothyronine (Ta), Thyroxine ff4), human Thyroid Stimulating Hormone (TSH), and Cortisol).
Matrix	Human Plasma	Human Serum

* From Instructions for Use

Conclusions:

The ADVIA® Centaur DHEAS Master Curve Material is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Maine Standards Company, VALIDATE Thyroid Calibration Verification Test Set (K062501) in intended use, matrix, and stability.

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 Clare Santulli
511 Benedict Avenue
Tarrytown, NY 10591

AUG 14 2009

Re: k091123
Trade/Device Name: ADVIA Centaur DHEAS Master Curve Materials
Regulation Number: 21 CFR § 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I (Reserved)
Product Code: JJX
Dated: June 11, 2009
Received: June 16, 2009

Dear Clare Santulli:

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.
Acting 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): K091123

Device Name(s): ADVIA CENTAUR® DHEAS Master Curve Material

Indications For Use:

The ADVIA® Centaur (DHEAS) Master Curve Material are for *in vitro* diagnostic use in the verification of calibration and reportable range in the ADVIA Centaur® Systems Dehydroepiandrosterone sulfate (DHEAS) assay.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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