K102904

510(k) Summary

Submitter information

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NOV 2 3 2010

Date summary prepared: September 29, 2010

Device Trade or Proprietary Name: ADVIA Centaur® Enhanced Estradiol (eE2) 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: _____

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® Enhanced Estradiol (eE2) Master Curve Material, Level 1 is buffer with bovine serum albumin and preservatives. Levels 2-6 are various levels of USP-Grade estradiol in lyophilized normal male serum with sodium azide (0.1% after reconstitution) and preservatives.
The eE2 Master Curve Materials have expected values (lot specific) of 0, 60, 175, 450, 1500 and 2700 pg/mL.

The eE2 Master Curve Material (1.0 mL/vial) are lyophilized material and stored 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® Enhanced Estradiol Master Curve Material is for *in vitro* diagnostic use in the verification of calibration and reportable range in the ADVIA Centaur® Enhanced Estradiol (eE2) assay.

Performance:

The traceability, value assignment, and stability of the ADVIA Centaur® Enhanced Estradiol Master Curve Materials have been validated following procedures of Siemens Healthcare Diagnostics. These Enhanced Estradiol 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*

	Device	Predicate
Item	ADVIA Centaur® Master Curve Material	Maine Standards Company VALIDATE Thyroid Calibration Verification Test Set (K062501)
Intended Use	The ADVIA Centaur® Enhanced Estradiol Master Curve Material is for *in vitro* diagnostic use in the verification of calibration and reportable range in the ADVIA Centaur® Enhanced Estradiol (eE2) 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	Lyophilized	Liquid
Analytes	Enhanced Estradiol only	Multiple analytes including Triiodothyronine (Ta), Thyroxine ff4), human Thyroid Stimulating Hormone (TSH), and Cortisol
Matrix	Human Serum	Human Serum
Storage	2°C to 8°C	-10°C to -20°C
Stability	**Unopened** – until expiration date on the vial label **Reconstituted** – 14 days or **On-board** – 6 hours	**Unopened** – until expiration date on storage container when stored as directed
Differences	Verification of calibration and reportable range for the ADVIA Centaur® Enhanced Estradiol assay.	Verification of calibration, linearity, and reportable range for multiple assays (Triiodothyronine (Ta), Thyroxine ff4), human Thyroid Stimulating Hormone (TSH), and Cortisol).

* From Instructions for Use

Conclusions:

The ADVIA Centaur® Enhanced Estradiol 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 and matrix.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Siemens Healthcare Diagnostics
c/o Clare Santulli
511 Benedict Avenue
Tarrytown, NY 10591 USA

Re: k102904
Trade Name: ADVIA Centaur Enhanced Estradiol (eE2) Master Curve Material
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed)
Regulatory Class: Class I, Reserved
Product Codes: JJX
Dated: November 5, 2010
Received: November 8, 2010

NOV 2 3 2010

Dear Ms. 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 Parts 801 and 809), 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 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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney 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

Indication for Use

NOV 2 3 2010

510(k) Number (if known) K102904

Device Name: ADVIA Centaur® Enhanced Estradiol (eE2) Master Curve Material

Indication For Use:

The ADVIA Centaur® Enhanced Estradiol (eE2) Master Curve Material is for *in vitro* diagnostic use in the verification of calibration and reportable range in the ADVIA Centaur® Enhanced Estradiol (eE2) assay.

Prescription Use ___√___ (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)

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

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