



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 Ms. Clare Santulli
Sr. Regulatory Specialist
511 Benedict Avenue
Tarrytown, NY 10591-5097

JAN 14 2010

Re: k091867
Trade name: ADVIA Centaur SHBG Ready Pack
Regulation Number: 21 CFR 862.1680
Regulation Name: Testosterone test system
Regulatory Class: Class I (reserved)
Product Code: CDZ, JIT, JJX
Dated: December 30, 2009
Received: December 31, 2009

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).

Page 2

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

Indication for Use

510(k) Number (if known): K091867

Device Name(s): ADVIA Centaur® SHBG Assay
 ADVIA Centaur® SHBG Calibrators
 ADVIA CENTAUR® SHBG Master Curve Material

Indication For Use:

The ADVIA Centaur® SHBG assay is an in vitro diagnostic immunoassay for the quantitative determination of sex hormone-binding globulin (SHBG) in human serum and plasma using the ADVIA Centaur systems.

The ADVIA Centaur SHBG assay is intended for use as an aid in the diagnosis of androgen disorders.

The ADVIA Centaur SHBG Calibrators are for in vitro diagnostic use in calibrating the ADVIA Centaur sex hormone-binding globulin (SHBG) assays.

The ADVIA Centaur SHBG Master Curve Material are for in vitro diagnostic use in the verification of calibration and reportable range in the ADVIA Centaur sex hormone-binding globulin (SHBG) 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)

Carol C. Benson

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

510(k) K091867