K081716

510(k) Summary
ADVIA Centaur® HAVM Assay

JUL 17 2008

1. Manufacturer's Name, Address, Telephone, and Contact Person

Manufacturer

Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, New York 10591-5097

Contact Information:

Mary Seeger
Manager, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, New York 10591-5097

Phone: 914-524-2908
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2. Date Summary Prepared:
June 10, 2008

3. Device Trade Name / Common Name

Common Name: IgM Antibody to Hepatitis A Virus (Anti-HAV IgM Assay)
Trade Name: ADVIA Centaur® HAV IgM ReadyPack Reagents
ADVIA Centaur® HAV IgM ReadyPack Calibrators
FDA Classification: Class II (special controls)

4. Device Classification Name: Hepatitis A Test IgM Antibody

5. Intended Use:
The ADVIA Centaur HAV IgM assay is an *in vitro* diagnostic immunoassay for the qualitative determination of IgM response to the hepatitis A virus (HAV) in human serum or plasma (EDTA, lithium heparinized, or sodium heparinized) using the ADVIA Centaur® System. This assay is intended for use as an aid in the diagnosis of acute or recent infection (usually 6 months or less) with hepatitis A virus.
Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients, cord blood, neonatal specimens, infants, or children.
WARNING: This assay has not been FDA cleared or approved for the screening of blood or plasma donors. United States federal law restricts this device to sale by or on the order of a physician.

6. **Device Description**

The modified ADVIA Centaur® HAV IgM Assay is comprised of the following:

1. ADVIA Centaur HAV IgM ReadyPack primary reagent pack is composed of three components:

- Lite Reagent - Mouse anti-HAV human IgM monoclonal antibody labeled with acridinium ester in buffer with bovine serum albumin and preservatives. The modified device uses the fab2 fragment of the monoclonal antibody
- Solid Phase - Streptavidin coated paramagnetic microparticles with bovine serum albumin and preservatives
- Ancillary Well Reagent - Inactivated purified hepatitis A virus (<0.1 ug/ml) in buffer with bovine serum albumin and preservatives

2. ADVIA Centaur HAV IgM Readypack ancillary reagent pack containing ADVIA Centaur HAV IgM Ancillary Reagent which is composed of biotinylated mouse monoclonal to anti-human IgM in buffer with bovine serum albumin and preservatives.
3. ADVIA Centaur HAV IgM Calibrators

7. **Substantial Equivalence**

The modified ADVIA Centaur HAV IgM assay has the same operating principles, design, method of manufacture, assay performance characteristics and intended use as the predicate device.

The modified ADVIA Centaur HAV IgM assay is substantially equivalent to the predicate ADVIA Centaur HAV IgM assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 17 2008

Siemens Healthcare Diagnostics Inc.
C/O Mary Seeger, Ph.D.
Manager, Regulatory Affairs
511 Benedict Avenue
Tarrytown, New York 10592

Re: k081716
Trade/Device Name: ADVIA Centaur HAVM Assay
Regulation Number: 21 CFR 866.3310
Regulation Name: Hepatitis A IgM
Regulatory Class: Class II
Product Code: LOL
Dated: June 16, 2008
Received: June 18, 2008

Dear Dr. Seeger:

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 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 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081716

Device Name: ADVIA Centaur® HAV IgM ReadyPack Reagents
ADVIA Centaur® HAV IgM Quality Control Materials

Indications for Use:

The ADVIA Centaur HAV IgM assay is an *in vitro* diagnostic immunoassay for the qualitative determination of IgM response to the hepatitis A virus (HAV) in human serum or plasma (potassium EDTA, lithium or sodium heparinized) using the ADVIA Centaur and ADVIA Centaur XP systems. This assay is intended for use as an aid in the diagnosis of acute or recent infection (usually 6 months or less) with hepatitis A virus.

Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients, cord blood, neonatal specimens, infants, or children.

WARNING: This assay has not been FDA cleared or approved for the screening of blood or plasma donors. United States federal law restricts this device to sale by or on the order of a physician.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Uwe Scherf

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K081716