510(k) Summary of Safety and Effectiveness

MAY - 4 2011

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92 and the Safe Medical Device Act of 1990.

The assigned 510(k) Number is: K102681

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

Manufacturer:	Siemens Healthcare Diagnostics Inc.
Address:	511 Benedict Avenue Tarrytown, NY 10591-5097
Contact Person:	Matthew Gee Senior Regulatory Specialist
Phone:	914-524-2099
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Email:	matthew.gee@siemens.com

2. Date Summary Prepared

June 11, 2010

3. Device Trade Name / Common Name / Classification Name

Trade Name:	ADVIA Centaur® Toxoplasma IgG (Toxo G) Assay
Common Name:	Immunoassay, Toxoplasma Gondii IgG
Classification Name:	Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii
FDA Classification:	Class II (Special Controls)
Review Panel:	Microbiology
Product Code:	LGD
Regulation Number:	866.3780

4. Predicate (Unmodified) Device

Device Name:	ADVIA Centaur® Toxoplasma IgG (Toxo G) Assay
Manufacturer:	Siemens Healthcare Diagnostics Inc. (previously Bayer Diagnostics Corp.)
510(k) Number:	K012183

5. Intended Use of Predicate (Unmodified) Device

The ADVIA Centaur Toxoplasma IgG assay is an IgG antibody capture microparticle direct *in vitro* diagnostic immunoassay intended for the quantitative and qualitative detection of IgG antibodies to the *Toxoplasma gondii* parasite in human serum or plasma (EDTA, heparin) using the ADVIA Centaur systems. The measurement of Toxoplasma IgG may be used to aid in the assessment of a patient's immunological response from individuals including women of childbearing age. This assay may be utilized with an IgM Toxoplasma result to determine recent serological response to Toxoplasma.

WARNING: The use of the ADVIA Centaur Toxoplasma IgG assay to diagnose recent infection by testing acute and convalescent samples is not recommended. The calculated values for toxoplasma IgG in a given specimen, as determined by assays from different manufacturers, can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the toxoplasma IgG assay used. Values obtained with different assay methods cannot be used interchangeably.

This assay has not been cleared or approved by the FDA for the screening of blood or plasma donors. Testing should not be performed as a screening procedure for the general population.

6. Intended Use of Modified Device

The ADVIA Centaur Toxoplasma IgG assay is an IgG antibody capture microparticle direct *in vitro* diagnostic immunoassay intended for the quantitative and qualitative detection of IgG antibodies to the *Toxoplasma gondii* parasite in human serum or plasma (EDTA, heparin) using the ADVIA Centaur systems. The measurement of Toxoplasma IgG may be used to aid in the assessment of a patient's immunological response from individuals including women of childbearing age. This assay may be utilized with an IgM Toxoplasma result to determine recent serological response to Toxoplasma.

WARNING: The use of the ADVIA Centaur Toxoplasma IgG assay to diagnose recent infection by testing acute and convalescent samples is not recommended. The calculated values for toxoplasma IgG in a given specimen, as determined by assays from different manufacturers, can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the toxoplasma IgG assay used. Values obtained with different assay methods cannot be used interchangeably.

This assay has not been cleared or approved by the FDA for the screening of blood or plasma donors. Testing should not be performed as a screening procedure for the general population.

7. Device Description

The modified ADVIA Centaur Toxo G Assay is comprised of the following:

ADVIA Centaur Toxo G ReadyPack® Primary Reagent Pack, including:

ADVIA Centaur Toxo G Lite Reagent (10.0 mL/reagent pack)

purified *T. gondii* p30 antigen (~0.75 µg/mL) complexed with mouse anti-p30 monoclonal antibody ($F(ab)_2$ fragment) labeled with acridinium ester in protein buffer with surfactant and preservatives

ADVIA Centaur Toxo G Solid Phase (25.0 mL/reagent pack)

mouse anti-human IgG_{Fc} monoclonal antibody (~0.3 mg/mL) covalently coupled to paramagnetic particles in protein buffer with surfactant and preservatives

ADVIA Centaur Toxo G Calibrators (1.0 mL/vial)

processed defibrinated human plasma positive for toxoplasma IgG antibodies with preservatives

ADVIA Centaur Toxo G Quality Control Material (2.7 mL/vial)

processed defibrinated human plasma negative and positive for toxoplasma IgG antibodies with preservatives

8. Similarities and Differences between Predicate and Modified Devices

Table 1. Similarities between Current and Modified ADVIA Centaur Toxo G Assays

Feature	Predicate (Unmodified) ToxoG Assay (K012183)	Modified ToxoG Assay
Intended Use	See Section 5	Same – See Section 6
Sample Type	Serum, Heparinized Plasma, EDTA Plasma	Serum, Heparinized Plasma, EDTA Plasma
Sample Volume	10 µL	10 µL
Assay Range	0.5–700 IU/mL	0.5–700 IU/mL
Performance Claims	See Instructions for Use	Unchanged

Table 2. Differences between Current and Modified ADVIA Centaur Toxo G Assays

Feature	Predicate (Unmodified) ToxoG Assay (K012183)	Modified ToxoG Assay
Lite Reagent Conjugate p30 Ag Concentration	1.5 µg/mL	0.75 µg/mL
Lite Reagent Conjugate Loading Ratio	30:1	18:1
Lite Reagent Antibody Format	Whole IgG	$F(ab)_2$ Fragment recognizing same epitope as current assay
Mouse IgG Concentration	*Lite Reagent Buffer* 800 mg/L *Solid Phase Buffer* none	*Lite Reagent Buffer* 400 mg/L *Solid Phase Buffer* 400 mg/L
PEG8000 in Solid Phase	none	20 g/L
Tween20 in Solid Phase	none	5 g/L

9. Substantial Equivalence

The modified ADVIA Centaur Toxo G assay has the same operating principles, assay performance characteristics and intended use as the predicate device.

The results of performance testing, and verification and validation activities demonstrate that the design modifications to the ADVIA Centaur Toxo G assay do not impact its safety or effectiveness and do not alter its performance claims. The modified assay is substantially equivalent to the currently-marketed predicate ADVIA Centaur Toxo G assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Siemens Healthcare Diagnostics Inc.
c/o Mr. Matthew Gee
Senior Regulatory Specialist
511 Benedict Avenue
Tarrytown, NY 10591-5097

MAY - 4 2011

Re: K102681
Trade/Device Name: ADIVA Centaur® Toxoplasma IgG (Toxo G) Assay
Regulation Number: 21 CFR 866.3780
Regulation Name: Toxoplasma gondii Serological Reagents
Regulatory Class: Class II
Product Code: LGD
Dated: April 13, 2011
Received: April 14, 2011

Dear Mr. Gee

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 class II (Special Controls), 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). 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 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,

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): K102681

Device Name: ADVIA Centaur® Toxoplasma IgG (Toxo G) Assay

Indications For Use:

The ADVIA Centaur Toxoplasma IgG assay is an IgG antibody capture microparticle direct *in vitro* diagnostic immunoassay intended for the quantitative and qualitative detection of IgG antibodies to the *Toxoplasma gondii* parasite in human serum or plasma (EDTA, heparin) using the ADVIA Centaur systems. The measurement of Toxoplasma IgG may be used to aid in the assessment of a patient's immunological response from individuals including women of childbearing age. This assay may be utilized with an IgM Toxoplasma result to determine recent serological response to Toxoplasma.

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 Device Evaluation (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K102681