K072794

Section 14 – 510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness information has been prepared in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

Establishment Names and Registration Numbers:

Siemens Medical Solutions Diagnostics
5210 Pacific Concourse Drive
Los Angeles, CA 90045-6900
Registration #: 3005250747

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Siemens Medical Solutions Diagnostics, Ltd.
Glyn Rhonwy
Llanberis, Caernarfon
Gwynedd, LL55 4EL
United Kingdom
Registration #: 3002806944

Telephone Number: (310) 645-8200 ext. 7524

Facsimile Number: (310) 645-9999

Contact Person: Maya Mahue-Giangreco, Ph.D.
Manager, Biostatistics

Date of Preparation: September 27, 2007

Device Trade Name: IMMULITE® 2500 OM-MA Immunoassay

Catalog Number: L5KOP

Device Common Name:
Reagent Reagent system for the measurement of CA 125 antigen in human sera.

Classification: Class II device; Product Code: LTK (21 CFR 866.6010)

21 CFR 866.6010: A tumor-associated antigen immunological test system is a device that consists of reagents used to qualitatively or quantitatively measure, by immunochemical techniques, tumor-associated antigens in serum, plasma, urine, or other body fluids. This device is intended as an aid in monitoring patients for disease progress or response to therapy or for the detection of recurrent or residual disease.

Panel: Immunology

CLIA Complexity Category: We believe the category to be moderate based on previous classification of analogous tests.

Manufacturer:

Siemens Medical Solutions Diagnostics
5210 Pacific Concourse Drive
Los Angeles, CA 90045-6900

Siemens Medical Solutions Diagnostics, Ltd.
Glyn Rhonwy
Llanberis, Caernarfon
Gwynedd, LL55 4EL
United Kingdom

Substantially Equivalent Predicate Device:

IMMULITE 2000 OM-MA Immunoassay (K983391)

Description of Device:

The IMMULITE 2500 OM-MA Immunoassay is a solid-phase, two-site, chemiluminescent immunometric assay for use with the IMMULITE 2500 Automated Analyzer.

Intended Use of the Device:

The IMMULITE 2500 OM-MA is intended for *in vitro* diagnostic use with the IMMULITE 2500 analyzer – for the quantitative measurement of CA125 antigen in serum, as an aid in monitoring the response to therapy for patients with epithelial ovarian cancer, and in detecting residual ovarian cancer in patients who have undergone first-line therapy and would be considered for diagnostic second-look procedures.

Conclusion:

The information presented in this Special 510(k) is that which the Food and Drug Administration used in granting Siemens Medical Solutions Diagnostics substantial equivalence for the IMMULITE 2500 OM-MA Immunoassay when compared with the IMMULITE 2000 OM-MA Immunoassay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV - 5 2007

Siemens Medical Solutions Diagnostics
c/o Maya Mahue-Giangreco, Ph.D.
Manager, Biostatistics
5210 Pacific Concourse Drive
Los Angeles, CA 90045

Re: k072794
Trade/Device Name: Immulite 2500 OM-MA and Tumor Marker Controls (TMC)
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-associated antigen immunological test system
Regulatory Class: Class II
Product Code: LTK, JJY
Dated: September 27, 2007
Received: October 1, 2007

Dear Dr. Mahue-Giangreco:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, 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" (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 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,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology 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): K072794

Device Name: Immulite 2500 OM-MA and Immulite Tumor Marker Controls

Indications For Use:
Immulite 2500 OM-MA
For in vitro diagnostic use with the IMMULITE 2500 Analyzer- for the quantitative measurement of CA125 antigen in human serum, as an aid in monitoring the response to therapy for patients with epithelial ovarian cancer and in detecting residual ovarian cancer in patients who have undergone first-line therapy and would be considered for diagnostic second-look procedures

Immulite Tumor Marker Controls
TMC is an assayed, serum-based, tri-level control containing analytes associated with malignancy which are commonly measured by immunoassay. It is intended strictly for in vitro use as an aid in monitoring the day-to-day performance of assays for these constituents.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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)

Maria M Chan
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K072794