# 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 Name:**

Siemens Medical Solutions Diagnostics
5700 West 96th Street
Los Angeles, CA 90045-5597

MAY - 2 2007

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

**Telephone Number:** (310) 645-8200

**Facsimile Number:** (310) 645-9999

**Contact Person:** Deborah L. Morris
Director, Clinical Affairs & Regulatory Submissions

**Date of Preparation:** April 6, 2007

**Device Trade Name:** IMMULITE® 2500 High Sensitivity C-Reactive Protein Immunoassay

**Catalog Number:** L5KCRP

**21 CFR 862.1377:** A C-reactive protein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the C-reactive protein in serum and other body fluids. Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues.

**Device Common Name:**

Reagent system for the determination of C-reactive protein in plasma or serum.

**Classification:** Class II device; Product Code: NQD (21 CFR 866.5270)

**Panel:** Immunology

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

**Manufacturer:** Siemens Medical Solutions Diagnostics
5700 West 96th Street
Los Angeles, CA 90045-5597

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

**Establishment Registration Number:**

Siemens Medical Solutions Diagnostics
5700 West 96th Street
Los Angeles, CA 90045-5597
Registration #: 2017183

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

**Substantially Equivalent Predicate Device:**

IMMULITE 2000 High Sensitivity C-Reactive Protein Immunoassay (K063057, K003372)

**Description of Device:**

The IMMULITE 2500 High Sensitivity C-Reactive Protein 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 High Sensitivity C-Reactive Protein Immunoassay is intended for *in vitro* diagnostic use with the IMMULITE 2500 analyzer for the quantitative measurement of C-reactive protein (CRP) in human serum or plasma, as an aid in the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases. Measurements may also be used as an aid in the identification of individuals at risk for future cardiovascular disease. High sensitivity CRP measurements, when used in conjunction with traditional clinical laboratory evaluation of acute coronary syndrome, may be useful as an independent marker for recurrent events in patients with stable coronary disease or acute coronary syndrome.

**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 High Sensitivity C-Reactive Protein Immunoassay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Siemens Medical Solutions Diagnostics
c/o Ms. Deborah L. Morris,
Director of Clinical Affairs & Regulatory Submissions
5210 Pacific Concourse Drive
Los Angeles, CA 90045-6900

MAY - 2 2007

Re: k071017
Trade/Device Name: IMMULITE® 2500 High Sensitivity C-Reactive Protein Immunoassay
Regulation Number: 21 CFR§ 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: Class II
Product Code: NQD
Dated: April 6, 2007
Received: April 10, 2007

Dear Ms. Morris:

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 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) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K071017

Device Name: IMMULITE® 2500 High Sensitivity C-Reactive Protein

Indications For Use:

The IMMULITE® 2500 High Sensitivity C-Reactive Protein Immunoassay is intended for use as follows:

For *in vitro* diagnostic use with the IMMULITE 2500 Analyzer — for the quantitative measurement of C-Reactive protein (CRP) in serum or plasma as an aid in the detection and evaluation of infection, tissue injury and inflammatory disorders and associated diseases. Measurements may also be used as an aid in the identification of individuals at risk for future cardiovascular disease. High sensitivity CRP (hsCRP) measurements, when used in conjunction with traditional clinical laboratory evaluation of acute coronary syndrome, may be useful as an independent marker for recurrent events in patients with stable coronary disease or acute coronary syndrome.

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 IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K071017