SIEMENS

K091361

DEC 16 2009

510(k) Summary as Required by 21 CFR 807.92

Submitter: Siemens Healthcare Diagnostics Inc.
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Director Regulatory Affairs
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Date Prepared: September 10, 2009

Device Trade Name: IMMULITE® 2000 Syphilis Screen

Common Name: Immunoassay for *Treponema pallidum*
21 CFR 866.3830

Substantial Equivalence: K061247
DiaSorin LIASION® Treponema Assay

Device Description: The IMMULITE 2000 Syphilis Screen is a solid-phase, one-step chemiluminescent immunoassay. The solid phase (bead) is coated with biotinylated recombinant *Treponema pallidum* p17 (Tp17) antigen. The liquid phase consists of alkaline phosphatase (bovine calf intestine) conjugated to purified recombinant *Treponema pallidum* p17 (Tp17) antigen.

The patient sample and reagent are incubated together with the coated bead for 30 minutes. During this time, total antibody to *Treponema pallidum* in the sample forms an antigen sandwich complex with biotinylated recombinant *Treponema pallidum* p17 (Tp17) antigen on the bead and enzyme conjugated purified recombinant *Treponema pallidum* p17 (Tp17) antigen in the reagent. Unbound patient sample and enzyme conjugate are then removed by centrifugal washes. Finally, chemiluminescent substrate is added to the reaction tube containing the bead and the signal is generated in proportion to the bound enzyme.

Intended Use: The IMMULITE® 2000 Syphilis Screen test is a treponemal testing procedure for the qualitative detection of antibodies to *Treponema pallidum* in human serum or heparinized plasma on the IMMULITE 2000 analyzer as an aid in the diagnosis of syphilis.

The IMMULITE 2000 Syphilis Screen is not intended for use in screening blood or plasma donors.

Technological Aspects: A comparison of the device features, intended use, laboratory data and other information demonstrate that the IMMULITE® 2000 Syphilis Screen is substantially equivalent to the currently marketed DiaSorin LIASION® Treponema Assay, as summarized in the following tables.

Table 1: Comparison of IMMULITE® with LIAISON® Assay

	IMMULITE 2000	LIAISON
Indications for Use	The IMMULITE® 2000 Syphilis Screen test is a treponemal testing procedure for the qualitative detection of antibodies to *Treponema pallidum* in human serum or heparinized plasma on the IMMULITE 2000 analyzer as an aid in the diagnosis of syphilis. The IMMULITE 2000 Syphilis Screen is not intended for use in screening blood or plasma donors.	The LIAISON Treponema assay uses chemiluminescence immunoassay (CLIA) technology for the qualitative detection of total antibodies directed against *Treponema pallidum* in human serum. The presence of antibodies to *Treponema pallidum* specific antigen, in conjunction with non-treponemal laboratory tests and clinical findings, may aid in the diagnosis of syphilis infection. The LIAISON Treponema Assay is not intended for use in screening blood or plasma donors.
Assay Type	Enzyme labeled, one-step chemiluminescent immunoassay	One-step sandwich chemiluminescent immunoassay
Capture/Detection Antigen/Antibody	Beads coated with purified recombinant *Treponema pallidum* p17 (TpN17) antigens are linked to enzyme conjugated purified recombinant *Treponema pallidum* p17 antigen in the reagent.	Magnetic particles coated with Tp17 DNA recombinant protein specific for *Treponema pallidum* are linked to an isoluminol derivative (isoluminol-antigen conjugate).
Cut-Offs	Test value = ratio of signal from sample to that of signal of adjustor curve parameter P1. ≥ 1.1 Reactive 0.9 to < 1.1 Indeterminate < 0.9 Non-reactive	Index value = ratio of signal from sample to that of the standard ≥ 1.1 Positive 0.9 to < 1.1 Equivocal < 0.9 Negative
Reportable Range	Qualitative Assay	Qualitative Assay

	IMMULITE 2000	LIAISON
Sample Volume	100 µL (plus dead volume)	220 µL (includes dead volume)
Cross-Reactivity	None observed with tested agents	None observed with tested organisms
Interference	Not affected by hemolysis, icterus or lipemia at test levels	Not affected by hemolysis, icterus or lipemia at test levels
Hook Effect	None observed	None observed

As part of the clinical study, samples from various patient populations were tested with both the IMMULITE Syphilis Screen and the LIAISON Treponema Assay. Results are summarized in the following tables.

Table 2: Method Comparison, Medically Diagnosed Syphilis Patients

Medically Diagnosed Syphilis Patients

	Liaison Treponema Assay			
Immulite Syphilis Assay	Equivocal	Negative	Positive	Total
Indeterminate	0	0	2	2
Non-Reactive	0	6	0	6
Reactive	1	2	270	273
Total	1	8	272	281

		95% Confidence Interval
Positive Agreement:	270/272=99.3%	97.4% - 99.9%
Negative Agreement:	6/8=75%	34.9% - 96.8%
Overall Agreement:	276/281=98.2%	95.9% - 99.4%

Table 3: Method Comparison, Samples Sent for Syphilis Testing

Samples Sent for Routine Syphilis Testing

	Liaison Treponema Assay			
Immulite Syphilis Assay	Equivocal	Negative	Positive	Total
Indeterminate	0	0	2	2
Non-Reactive	0	558	0	558
Reactive	0	5	359	364
Total	0	563	361	924

		95% Confidence Interval
Positive Agreement:	359/361=99.4%	98.0% - 99.9%
Negative Agreement:	558/563=99.1%	97.9% - 99.7%
Overall Agreement:	917/924=99.2%	98.4% - 99.7%

Precision/ reproducibility information in the product insert for the LIAISON Treponema Assay shows between-site coefficients of variation (CV) ranging from 4.32% to 17.76% for the 11 samples reported. The reproducibility of the IMMULITE Syphilis Screen as measured by between-site CV ranged from 7.1% to 22.6% for Lot 1 and from 6.1% to 29.7% for Lot 2. Seven samples were tested with both IMMULITE lots.

A comparison of the device features, intended use, laboratory data and other information demonstrates that the IMMULITE® 2000 Syphilis Screen is substantially equivalent to the currently marketed DiaSorin LIASION® Treponema assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

DEC 16 2009

Ms. Carolyn K. George
C/o Independent Consultant
Siemens Healthcare Diagnostics
6695 River Crest Point
Suwanee, Georgia 30024

Re: k091361
Trade/Device Name: IMMULITE® 2000 Syphilis Screen
Regulation Number: 21 CFR § 866.3830
Regulation Name: *Treponema pallidum* treponemal test reagents
Regulatory Class: II
Product Code: LIP
Dated: September 10, 2009
Received: September 14, 2009

Dear Ms. George:

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.

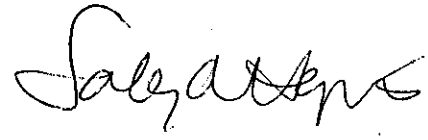
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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 (301) 796-5455. 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 (301) 443-6597 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 Form

510(k) Number (if known): **K091361**

Device Name: **IMMULITE® 2000 Syphilis Screen**

Indications for Use:
The IMMULITE® 2000 Syphilis Screen test is a treponemal testing procedure for the qualitative detection of antibodies to *Treponema pallidum* in human serum or heparinized plasma on the IMMULITE 2000 analyzer as an aid in the diagnosis of syphilis.

The IMMULITE 2000® Syphilis Screen is not intended for use in screening blood or plasma donors.

Prescription Use ✓
(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 In Vitro Diagnostic Devices (OIVD)

Freddie M. Poole

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

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