510(k) Summary as Required by 21 CFR 807.92

Submitter: Siemens Healthcare Diagnostics Inc.
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Los Angeles, CA 90045-6900

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Director Regulatory Affairs
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(916) 374-3183

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 LIASON® Treponema Assay, as summarized in the following tables.

Table 1: Comparison of IMMULITE® with LIASON® Assay

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

<table>
<thead>
<tr>
<th>Medically Diagnosed Syphilis Patients</th>
<th>IMMULITE® 2000</th>
<th>LIAISON</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Equivocal</td>
<td>Negative</td>
<td>Positive</td>
</tr>
<tr>
<td>Indeterminate</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>1</td>
<td>8</td>
<td>272</td>
</tr>
</tbody>
</table>

### Table 3: Method Comparison, Samples Sent for Syphilis Testing

<table>
<thead>
<tr>
<th>Samples Sent for Routine Syphilis Testing</th>
<th>IMMULITE® 2000</th>
<th>LIAISON</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Equivocal</td>
<td>Negative</td>
<td>Positive</td>
</tr>
<tr>
<td>Indeterminate</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>0</td>
<td>5</td>
<td>359</td>
</tr>
</tbody>
</table>

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.
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 ✓ AND/OR Over-The-Counter Use (21 CFR 801 Subpart C)
(Part 21 CFR 801 Subpart D)

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

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

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

510(k) K091361

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