K992552

DEC 16 1999

December 10, 1999

510(K) SUMMARY

SUBMITTED BY: Judith J. Smith
Vice President,
Worldwide Regulatory Affairs and Quality Systems

NAME OF DEVICES:

Trade Name: Copalis Treponemal Antigen Total Antibody Assay

Common Names/Descriptions: Immunoassay for the Detection of Total Antibodies to *Treponema pallidum*

Classification Names: Treponema pallidum treponemal test

PREDICATE DEVICES: Zeus Scientific Inc. FTA-ABS and FUJIREBIO INC. SERODIA® TP-PA

DEVICE DESCRIPTION:

INTENDED USE: The Copalis Treponemal Antigen Total Antibody Assay uses Coupled Particle Light Scattering (Copalis®) technology in a microparticle agglutination-based immunoassay for the qualitative detection of total antibodies (IgG and IgM) to recombinant *Treponema pallidum* antigens in human serum using the Copalis I Immunoassay System. The presence of antibodies is indicative of current or prior infection with *T. pallidum.* The assay is indicated as an aid in the confirmation of syphilis disease following a positive result with a nontreponemal screening test. This assay has not been FDA cleared or approved for the screening of blood or plasma donors.

KIT DESCRIPTION: The Copalis® Treponemal Antigen Total Antibody Assay is based on Coupled Particle Light Scattering (Copalis) technology which provides a rapid method for the measurement of antibodies to specific pathogens.

The assay is a microparticle agglutination test using the Copalis light scattering technology. Polystyrene microparticles are coated with recombinant antigen derived from *T. pallidum* and are contained within a special covered reaction well in the test cup. The dried reagent is reconstituted with a reaction buffer on the instrument at the start of the assay. Patient sample is added to the reaction mixture and incubated for 10 minutes. The presence of antibodies specific to *T. pallidum* in the patient sample results in agglutination of the monomer microparticles to form aggregrates. The reaction mixture is passed through a flow cell and the instrument uses light scattering technology to measure the monomer concentration. The decrease in the monomer population resulting from agglutination is related to the amount of antibody in the sample. The residual monomer concentration in each reaction mixture is compared to a cutoff value to determine sample reactivity and nonreactivity.

PERFORMANCE DATA:

Clinical Correlation: Clinical trials were conducted at four sites (2 clinical laboratories, 1 reference laboratory and the laboratory located at DiaSorin Inc.) to evaluate the performance of the Copalis Treponemal Antigen Total Antibody Assay in detecting antibodies to *Treponema pallidum* on the Copalis I Immunoassay System. The assay performance was compared to the Zeus Scientific Inc. FTA-ABS assay and the FUJIREBIO Inc. TP-PA, both of which are confirmatory tests.

Samples from 188 patients with diagnosis of syphilis were analyzed using the Copalis® Treponemal Antigen Total Antibody Assay. These samples were characterized by disease state and treatment status. The clinical sensitivity of the assay is shown below.

Clinical Sensitivity and 95% Confidence Limits From Syphilitic Sera:

Stage	Treatment Status	Copalis Sensitivity RPR + FTA +	Copalis Sensitivity RPR – FTA +	Copalis Specificity RPR +/- FTA -
Primary	Untreated	100% (15.8–100%)	--	100% (2.5-100%)
	Treated	100% (75.3-100%)	66.7% (22.2-95.7%)	100% (2.5-100%)
Secondary	Untreated	100% (86.3-100%)		--
	Treated	100% (88.1-100%)	100% (2.5-10%)	--
Latent	Treated	97.8% (92.2-99.7%)	100% (66.4-100%)	100% (15.8-100%)
Late, Cardiovascular		100% (29.2-100%)	100% (2.5-100%)	--
Congenital		100%* (15.8-100%)	100% (15.8-100%)	--

*excludes 1 equivocal result

In addition, 2086 sera from a variety of diseases and 45 CDC or commercial panel samples were tested. The results are summarized below.

Category	Number	Agreement
RPR positive samples sent to hospital laboratories for confirmation of disease	1005	96.3% (944/980) (25 equivocal)
Apparently healthy adults	1002	Prevalence: Copalis = 3.2% (32/1002) FTA = 2.2% (22/1002)
Other (Obstetric; Pediatric >18 months old)	35	100% (34/34) (1 Copalis eq/FTA -)

Category	Number	Agreement
CDC Panel	20	90% (18/20)
Characterized commercial syphilis mixed titer panel	25	100% (25/25)

Reproducibility: Reproducibility studies were performed at the 3 sites using one lot of reagents. Assay reproducibility was determined by testing 6 samples that spanned the range of the assay's CTRs. Samples were tested in duplicate once a day for 5 days. The results are summarized below.

COPALIS TREPONEMAL ASSAY REPRODUCIBILITY RESULTS COMBINED SITES CTR

SAMPLE	MEAN CTR	WITHIN RUN %CV	TOTAL %CV
Negative Control	101	-	1.4
Positive Control	171	-	8.7
RP1	103	1.4	1.9
RP2	1470	16.2	18.0
RP3	101	1.5	1.8
RP4	280	13.1	16.7
RP5	1068	12.9	16.7
RP6	172	7.6	13.3

The Copalis TTA Quality Control procedures include the running of a negative and a positive control at least every 24 hours of use. This procedure was followed by all sites during the clinical trials. A summary of the control data is presented here.

CONTROL RESULTS, SITES COMBINED

	Mean CTR	%CV
Negative Control	100.2	2.0%
Positive Control	165.2	7.6%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 16 1999

Ms. Judith J. Smith
Vice President
Worldwide Regulatory Affairs and Quality Systems
DiaSorin, Inc.
9175 Guilford Road
Quarry Park Place, Suite 100
Columbia, Maryland 21046

Re: K992552
Trade Name: DiaSorin Copalis™ Treponemal Antigen Total Antibody Assay
Regulatory Class: II
Product Code: LIP
Dated: October 20, 1999
Received: October 25, 1999

Dear Ms. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 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 Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): **K992552**

Device Name: DiaSorin Copalis® Treponemal Antigen Total Antibody Assay

Indications For Use:

The Copalis Treponemal Antigen Total Antibody Assay uses Coupled Particle Light Scattering (Copalis®) technology in a microparticle agglutination-based immunoassay for the qualitative detection of total antibodies (IgG and IgM) to recombinant *Treponema pallidum* antigens in human serum using the Copalis I Immunoassay System. The presence of antibodies is indicative of current or prior infection with *T. pallidum.* The assay is indicated as an aid in the serological confirmation of syphilis disease following a positive result with a nontreponemal screening test. This assay has not been FDA cleared or approved for the screening of blood or plasma donors.

NOTE: The Copalis Treponemal Antigen Total Antibody Assay has not been evaluated as an initial or single test for the serodiagnosis of syphilis. The predictive value of a positive Copalis Treponemal Antigen Total Antibody Assay result has not been determined with RPR negative specimens.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992552

Prescription Use X OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)