K982027

NOV 25 1998

November 23, 1998

510(k) Summary

SUBMITTED BY:

Judith J. Smith
DiaSorin Inc.
9175 Guilford Rd. Suite 100
Columbia, MD 21046

NAME OF DEVICES:

Trade Name:	Copalis® CMV Total Antibody Assay
Common Names/Descriptions:	Immunoassay for the Detection of Total Antibodies to Cytomegalovirus
Classification Names:	Cytomegalovirus serological reagents

PREDICATE DEVICES:

Copalis® CMV Total Antibody Assay, Abbott CMV Total AB EIA, Becton Dickinson CMVscan

DEVICE DESCRIPTION:

INTENDED USE: (NOTE: This is an exerpt of the Intended Use which appears in the package insert and deals specifically with CMV). The Copalis® CMV 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 cytomegalovirus (CMV) in human serum using the Copalis® One Immunoassay System. The presence of antibodies is indicative of current or prior infection with the suspected organism. When evaluating properly paired sera, the results of this assay are used to demonstrate seroconversion as evidence of recent infection. Both specimens should be tested simultaneously. The assay can also be used to determine the CMV immune status of transplant donors and recipients. Assay results from immunosuppressed individuals must be interpreted with caution since their antibody levels may be affected by this condition. This assay has not been FDA cleared or approved for the screening of blood or plasma donors.

KIT DESCRIPTION: Coupled Particle Light Scattering (Copalis) technology provides a rapid method for the measurement of antibodies to specific viral or protozoal pathogens.

The Copalis® CMV Total Antibody Assay is based on the principle of antibody-dependent particle aggregation as detected by measurement of changes in light scattering. Sized latex microparticles coated with inactivated

CMV antigens aggregate in the presence of antibodies to CMV. After 10 minutes of agitation, the levels of aggregation are determined by discrimination of particle sizes and measurement of the number of reacted and unreacted particles as they flow past a detector. Reactivity is assessed by the level of aggregation per particle size relative to a cutoff value. The Copalis® CMV Total Antibody Assay detects the presence of both IgM and IgG antibodies. Two levels of controls are used to monitor proficiency.

PERFORMANCE DATA:

Clinical Sample Testing: Clinical sample testing was conducted at 2 hospital laboratories. The Copalis® CMV Total Antibody Assay was compared to the Abbott CMV Total AB EIA and the Becton Dickinson CMVscan.

A total of 205 serum samples were tested. The samples included both transplant donors and recipients. In initial testing, relative sensitivity of the CMV assay was 100% in both the transplant donor and recipient population. The relative specificity was 100% in the transplant recipient population and 93.7% in the donor population. Agreement was 100% and 96.7% in the transplant recipient and donor populations, respectively. Two of the four false positive results observed on initial testing of transplant donors by the Copalis® system were concordant positive on retest. The resulting agreement was 121/123 (98.4%).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 25 1998

Judith J. Smith
Corporate Director
Worldwide Regulatory Affairs
and Quality Systems
DiaSorin Inc.
9175 Guilford Rd., Suite 100
Columbia, MD 21046

Re: K982027
Trade Name: Modification to Copalis CMV Total Antibody Assay
Regulatory Class: II
Product Code: LFZ
Dated: September 11, 1998
Received: September 14, 1998

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): Not known

Device Name: Copalis™ TORC Total Antibody Assay, Copalis CMV Total Antibody Assay;

Indications For Use: The Copalis™ TORC Total Antibody Assay is used for the qualitative detection of total antibodies (IgG and IgM) to *Toxoplasma gondii*, rubella and cytomegalovirus in men and women of child-bearing age. The Copalis™ CMV Total Antibody Assay is used for the qualitative detection of total antibodies (IgG and IgM) to cytomegalovirus in men and women of child-bearing age. The presence of antibodies in these populations is indicative of recent or prior infection. These assays are not intended for screening of blood or plasma donors. The Copalis™ TORC Total Antibody Assay and the Copalis™ CMV Total Antibody Assay can be used in both the clinical and physician office laboratories. These assays can also be used to determine the CMV immune status of transplant donors and recipients.

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K982027

PRESCRIPTION USE X