DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DiaSorin S.r.l.
c/o Ms. Judi Smith
Regulatory and Quality Assurance Consultant
Sienna Partners, LLC
P.O. Box 103
Baldwin, MD 21013

MAR 30 2001

Re: P990044
DiaSorin ETI-CORE-IGMK PLUS Assay
Filed: July 2, 1999
Amended: September 9 and September 30, 1999; February 3, February 8, April 26, June 13, and June 19, 2000; and March 27, 2001

Dear Ms. Smith:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the DiaSorin ETI-CORE-IGMK PLUS Assay. This device is indicated for:

> ETI-CORE-IGMK PLUS is an *in vitro* enzyme immunoassay (EIA) intended for use in the qualitative determination of IgM antibody to hepatitis B core antigen (IgM anti-HBc) in human serum or plasma (EDTA, citrate or heparin). The ETI-CORE-IGMK PLUS is intended for manual use and with the Biochem Immunosystems Labotech/ETI-LAB automated instrument.
>
> The presence of IgM anti-HBc, in the presence of total antibody to HBc (anti-HBc), is indicative of a laboratory diagnosis for acute infection. The absence of IgM anti-HBc, in the presence of total anti-HBc, is indicative of a laboratory diagnosis for recovery from HBV infection. Further HBV serological marker testing is required to define the specific disease state.
>
> The ETI-CORE-IGMK PLUS assay's performance has not been established for the monitoring of HBV disease or therapy. This assay has not been FDA-approved for the screening of blood or plasma donors.

We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109. Expiration dating for this device when stored at 2 - 8 °C has been established and approved at 7 months.

In addition to the postapproval requirements in the enclosure, the following two postapproval studies are required:

1. Within 6 months of this approval, you must submit a reproducibility study for the Biochem Immunosystems Labotech/ETI-Lab automated instrument.

2. To address the concerns made by the FDA advisory panel regarding the retrospective nature of your clinical studies, within 2 years of this approval, we request you submit the results of an additional prospective clinical study. This study should involve individuals that may be considered representative of an U.S. population, i.e., similar prevalence of HBV disease and serotypes.

3. Within 6 months of approval, we request that you submit a plasma reproducibility study for the ETI-CORE-IGMK PLUS assay.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet Home Page located at http://www.fda.gov/cdrh/pmapage.html. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, Maryland 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. As part of our reengineering effort, the Office of Device Evaluation is piloting a new process for review of final printed labeling. The labeling will not routinely be reviewed by FDA staff when PMA applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment. Please see the CDRH Pilot for Review of Final Printed Labeling document at http://www.fda.gov/cdrh/pmat/pilotpmat.html for further details.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Mr. Thomas E. Simms or Mr. Peter L. Summers at (301) 594-2096.

Sincerely yours,

S. Gutman

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

Enclosure