

Special 510(k): Device Modification: Transferrin SPQ™ III Antibody Reagent Set

10 510(k) Summary

October 30, 1998

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

Name Of Device:
 Trade Name: Transferrin SPQ™ III Antibody Reagent Set
 Common Name: Transferrin (TRF) Immunological Test Kit
 Classification Name: Transferrin, antigen, antiserum, Control (82 DDG)

Device Classification Class II

Predicate Device: SPQ™ Antibody Reagent Set II for Transferrin

Device Description: Transferrin (TRF) Immunological Test Kit

Intended Use: FOR IN VITRO DIAGNOSTIC USE.
 The Transferrin SPQ™ III ANTIBODY REAGENT SET is designed for the quantitative determination of transferrin in human serum by immunoprecipitin analysis.

Technological Comparison: The modified device has the same technological basis as the predicate device.

Labeling Comparison: The labeling of the modified assay is substantially equivalent to that of the predicate device. Changes in labeling directly reflect the device modification (higher titer primary antibody, elimination of patient sample diluent).

Nonclinical Testing: Nonclinical testing demonstrated that the performance characteristics of the modified device were substantially equivalent to those of the predicate device.

Clinical Testing: Clinical testing demonstrated that the performance characteristics of the modified device were substantially equivalent to those of the predicate device.

Conclusions from Testing: The modified device is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 18 1998

Ms. Judith J. Smith
Corporate Director
Worldwide Regulatory Affairs
And Quality Systems
DiaSorin, Inc.
9175 Guilford Road, Suite 100
Columbia, Maryland 21046

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Re: K983880
Trade Name: Transferrin SPQ™ III Antibody Reagent Set
Regulatory Class: II
Product Code: DDG
Dated: October 30, 1998
Received: November 2, 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.

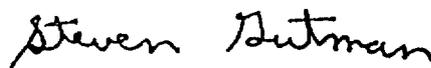
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2

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 (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



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

