NOV 16 1998

K983617

Special 510(k): Device Modification (cont.)
25-Hydroxyvitamin D ^{125}I RIA Kit

8. 510(k) Summary

November 16, 1998

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

Name Of Device:
Trade Name: 25-Hydroxyvitamin D ^{125}I RIA Kit

Common Name: Vitamin D Test System

Classification Name: Vitamin D Test System

Device Classification Class II

Predicate Device: 25-Hydroxyvitamin D ^{125}I RIA Kit, K953567, by DiaSorin, Inc.

Device Description: Immunoassay kit for quantitative determination of 25-hydroxyvitamin D

Intended Use: FOR IN VITRO DIAGNOSTIC USE.
This kit intended for the quantitative determination of 25-hydroxyvitamin D (25-OH-D) and other hydroxylated vitamin D metabolites in human serum or plasma to be used in the assessment of vitamin D sufficiency. Assay results should be used in conjunction with other clinical and laboratory data to assist the clinician in making individual patient management decisions in an adult population.

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 and the resultant improvements in analytical sensitivity and precision.

Nonclinical Testing: Verification and validation testing demonstrated that the performance characteristics of the modified device equaled or surpassed those of the predicate device.

Clinical Testing: Verification and validation testing including the use of patient serum samples and demonstrated that the performance characteristics of the modified device equaled or surpassed those of the predicate device.

Conclusions from Testing: The modified device is substantially equivalent to the predicate device and demonstrates improved analytical sensitivity and precision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 16 1998

Ms. Judith J. Smith
Corporate Director,
Worldwide Regulatory Affairs/Quality Systems
Diasorin, Inc.
9175 Guilford Rd., Suite 100
Quarry Park Place
Columbia, MD 21046

Re: K983617
25-Hydroxyvitamin D125I RIA
Regulatory Class: II
Product Code: LCI
Dated: October 12, 1998
Received: October 15, 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 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 (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

Special 510(k): Device Modification (cont.)
25-Hydroxyvitamin D ^{125}I RIA Kit

3. Indications for Use

510(k) Number: K983617

Device Name: 25-Hydroxyvitamin D ^{125}I RIA Kit

Indications For Use:

FOR IN VITRO DIAGNOSTIC USE.
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983614