MAR - 1 2001

K003329

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
AUTO D-Dimer Control Level 2, Cat. No. A5217

Sigma Diagnostics ACCUMARK AUTO D-Dimer Control Level 2 is a human plasma control that is suitable for use as a elevated control with patient citrated plasma in the Sigma Diagnostics AUTO D-dimer assay.

The safety and effectiveness of the Sigma Diagnostics AUTO D-Dimer Control Level 2 has been demonstrated by its substantial equivalence to the Dade Behring Advanced D-Dimer Control Plasma (K992957).

Sigma Diagnostics AUTO D-Dimer Control Level 2 is a lyophilized human plasma based product. After reconstitution with water, AUTO D-Dimer Control Level 2 is stable for 3 days when stored at 2-8°C.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR - 1 2001

William R. Gilbert, Ph.D.
Manager, Scientific Affairs
Sigma Diagnostics, Inc.
545 South Ewing Avenue
St. Louis, Missouri 63103

Re: K003329
Trade Name: Sigma Diagnostics AUTO D-Dimer Control, Level 2
Regulatory Class: II
Product Code: GGC
Dated: February 5, 2001
Received: February 14, 2001

Dear Dr. Gilbert:

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.

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" (21CFR 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 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): K003329

Device Name: Sigma Diagnostics AUTO D-Dimer Control, Level 2

Indications For Use:

Sigma Diagnostics ACCUMARK AUTO D-Dimer Control Level 2 is a human plasma control that is suitable for use as an abnormal control with patient citrated plasma in D-dimer agglutination assays. Plasma controls are routinely used in the coagulation laboratory as a means of quality control.

Valerie R. Duda (acting)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K00 3329

(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)