K971260

OCT 20 1997

510(k) NOTIFICATION

Sigma Diagnostics Inc.
June 12, 1997

CS-400™ Coagulation Analyzer
Catalog No. A1208

510(k) Summary of Safety and Effectiveness

The Amelung CS-400™ Coagulation Analyzer is an automated random access multipurpose analyzer. The CS-400™ Coagulation Analyzer can be used for the detection of fibrin formation utilizing either mechanical principles (ball method) or photo-optical principles to perform clot based tests such as prothrombin time (PT), activated partial thromboplastin time (APTT), fibrinogen, factor assays, and other clotting tests. In addition, the CS-400™ Coagulation Analyzer can be used for chromogenic assays such as antithrombin III (AT III).

In comparison studies of assays between the CS-400™ Coagulation Analyzer and the Amelung AMAX CS-190™ Coagulation Analyzer, the following regression statistics were obtained:

PT (optical)	r = 0.921	y = 1.061x + 0.6
PT (mechanical)	r = 0.924	y = 1.038x - 0.5
APTT (optical)	r = 0.964	y = 1.072x - 0.5
APTT (mechanical)	r = 0.972	y = 0.938x + 1.0
Factor IX (optical)	r = 0.945	y = 0.943x + 4.6
Factor IX (mechanical)	r = 0.924	y = 0.977x + 3.7
Factor X (optical)	r = 0.966	y = 0.920x + 9.5
Factor X (mechanical)	r = 0.974	y = 0.898x + 8.7
Fibrinogen (optical)	r = 0.967	y = 1.064x - 11.3
Fibrinogen (mechanical)	r = 0.977	y = 1.074x - 2.2
AT III (chromogenic)	r = 0.972	y = 0.920x + 11.7

The following coefficients of variation were obtained from precision studies:

	Within Run	Total
PT (optical)	<2.2%	<4.5%
PT (mechanical)	<3.2%	<6.5%
APTT (optical)	<2.5%	<3.5%
APTT (mechanical)	<2.3%	<3.5%
Factor IX (optical)	<5.3%	<7.3%
Factor IX (mechanical)	<6.3%	<9.5%
Factor X (optical)	<5.7%	<7.8%
Factor X (mechanical)	<3.8%	<7.0%
Fibrinogen (optical)	<5.1%	<8.1%
Fibrinogen (mechanical)	<5.9%	<9.0%
AT III (chromogenic)	<5.9%	<9.3%

The safety and effectiveness of the CS-400™ Coagulation Analyzer is demonstrated by its substantial equivalency to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 20 1997

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

Re: K972260
CS-400™ Coagulation Analyzer System
Regulatory Class: II
Product Code: JPA
Dated: August 21, 1997
Received: August 22, 1997

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 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

510(k) Number (if known): _____

Device Name: CS-400™ Coagulation Analyzer

Indications For Use:

The CS-400™ Coagulation Analyzer is a multipurpose system for in vitro coagulation studies consisting of one automated instrument and its associated reagents and controls. The system is used to perform a series of coagulation studies and coagulation factor assays.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K979260

Prescription Use ✓ OR **Over-The-Counter Use** ____
(Per 21 CFR 801.109)