510(k) Summary of Safety and Effectiveness

K021162

AUG 3 0 2002

Submitted by: Sigma Diagnostics
545 South Ewing Av
St. Louis, MO 63103

Contact Person: William R. Gilbert, Ph.D.
Manager, Scientific Affairs
314-286-6693

Preparation Date: July 12, 2002

Device Name: AMAX Destiny™ Coagulation Analyzer

Device Classification: JPA, Multipurpose system for in vitro coagulation studies, Class II (864.5425)

The AMAX Destiny™ Coagulation Analyzer is an automated random access multipurpose analyzer. The AMAX Destiny™ 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 AMAX Destiny™ Coagulation Analyzer can be used for chromogenic assays such as antithrombin III (AT III) and for microparticle agglutination assays such as d-dimer.

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

PT (optical)	$r = 0.993$	$y = 1.223x - 1.5$
PT (mechanical)	$r = 0.994$	$y = 1.180x - 2.5$
APTT (optical)	$r = 0.913$	$y = 1.191x - 1.2$
APTT (mechanical)	$r = 0.923$	$y = 1.112x - 2.3$
Factor IX (optical)	$r = 0.977$	$y = 0.928x + 3.8$
Factor IX (mechanical)	$r = 0.964$	$y = 0.880x + 3.9$
Factor X (optical)	$r = 0.982$	$y = 0.935x + 3.3$
Factor X (mechanical)	$r = 0.972$	$y = 0.957x + 2.5$
Fibrinogen (optical)	$r = 0.978$	$y = 0.974x + 27.3$
Fibrinogen (mechanical)	$r = 0.968$	$y = 1.069x - 14.5$
Thrombin time (mechanical)	$r = 0.990$	$y = 0.965x + 1.5$
AT III (chromogenic)	$r = 0.934$	$y = 1.070x - 8.8$
D-dimer (agglutination)	$r = 0.995$	$y = 1.121x - 57.0$

The following coefficients of variation were obtained from precision studies:

	Within Run	Total
PT (optical)	<2.0%	<3.8%
PT (mechanical)	<1.2%	<3.8%
APTT (optical)	<1.4%	<2.1%
APTT (mechanical)	<1.3%	<2.3%
Factor IX (optical)	<4.4%	<7.2%
Factor IX (mechanical)	<4.3%	<8.4%
Factor X (optical)	<3.0%	<5.9%
Factor X (mechanical)	<4.7%	<8.8%
Fibrinogen (optical)	<2.3%	<4.7%
Fibrinogen (mechanical)	<4.1%	<5.4%
Thrombin time (mechanical)	<2.0%	<3.6%
AT III (chromogenic)	<2.9%	<5.2%
D-dimer (agglutination)	<13.3%	<33.0%

The safety and effectiveness of the AMAX Destiny™ Coagulation Analyzer is demonstrated by its substantial equivalency to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 3 0 2002

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

Re: k021162
Trade/Device Name: AMAX Destiny™ Coagulation Analyzer
Regulation Number: 21 CFR § 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: II
Product Code: JPA
Dated: July 12, 2002
Received: July 16, 2002

Dear Dr. Gilbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 International and Consumer 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): K021162

Device Name: AMAX Destiny™ Coagulation Analyzer

Indications For Use:

The AMAX Destiny™ 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.

Josephine Bautista

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021162

(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)