K031377

SEP - 8 2003

510(k) Summary of Safety and Effectiveness Information
Sysmex® Automated Coagulation Analyzer CA-500
April 30, 2003

I. MANUFACTURER AND CONTACT INFORMATION

Contact Information:

Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101
Attn: Radames Riesgo
Phone: 305.480.7558
FAX: 305.552.5288

Registration Number:

Manufacturing Site
Sysmex Corporation
Kobe, Japan 9613959

Importer
Sysmex Corporation of America
One Wildlife Way
Long Grove, IL 60047-9596 1422681

Distributer
Dade Behring Inc.
Glasgow Site
P.O. Box 6101
Newark, DE 19714-6101 2517506

II. DEVICE NAME AND CLASSIFICATION NAME

Trade or Proprietary Name: Sysmex® Automated Coagulation Analyzer CA-500

Common or Usual Name: Automated Coagulation System

Classification Name: Coagulation Instrument (21 CFR §864.5400)

III. IDENTIFICATION OF THE LEGALLY MARKETED DEVICE

Sysmex® Automated Coagulation Analyzer CA-7000 (K020979)
Sysmex® Automated Coagulation Analyzer CA-6000 (K964139)

IV. DEVICE DESCRIPTION

The Sysmex® CA-500 series is a fully automated, computerized blood plasma coagulation analyzer for in *vitro* diagnostic use in clinical laboratories. The manufacturer has modified the series to include two new models with immunological testing capability. The proposed Sysmex CA-500 series can now provide accurate and precise test results for up to five parameters simultaneously and in random access. The CA-500 uses clot, chromogenic and immunological detection technologies for determination of the various parameters.

V. DEVICE INTENDED USE

The intended use of the Sysmex® CA-500 is as a fully automated, computerized blood plasma coagulation analyzer for *in vitro* diagnostic use in clinical laboratories. The instrument uses citrated human plasma to perform coagulation tests.

VI. SUBSTANTIAL EQIVALENCE

The Sysmex® Automated Coagulation Analyzer CA-550 or CA-560 is substantially equivalent in intended use for D-Dimer testing to the Sysmex® Automated Coagulation Analyzer CA-7000, which was cleared under Document Control No. K020979.

The results of PT and APTT parameters using the new software version for the Sysmex® Automated Coagulation Analyzer CA-500 Series are substantially equivalent to the results for PT and APTT parameters obtained with the Sysmex® Automated Coagulation Analyzer CA-6000, which was cleared under Document Control No. K964139.

VII. DEVICE PERFORMANCE CHARACTERISTICS

Summary of Method Comparison Studies between CA-500 and CA-7000 or CA-6000

Test	Predicate Device	Sample Number (n)	Coefficient of Correlation (r)	Regression Equation
D-Dimer Assay (Advanced D-Dimer)	CA-7000	390	0.992	Y = 1.01X + 0.14
PT, seconds (Thromborel® S)	CA-6000	248	0.999	Y = 1.00X – 0.50
PT, INR (Thromborel® S)	CA-6000	248	0.999	Y = 0.89X + 0.11
Derived Fibrinogen (Thromborel® S)	CA-6000	248	0.998	Y = 1.08X + 0.04
PT, seconds (Innovin®)	CA-6000	243	0.999	Y = 1.03X – 0.26
PT, INR (Innovin®)	CA-6000	243	0.999	Y = 1.08X – 0.09
Derived Fibrinogen (Innovin®)	CA-6000	247	0.995	Y = 1.09X – 0.17
PT, seconds (Thromboplastin C Plus	CA-6000	245	0.997	Y = 1.00X – 0.20
PT, INR (Thromboplastin C Plus)	CA-6000	245	0.998	Y = 1.00X – 0.00
Derived Fibrinogen (Thromboplastin C Plus)	CA-6000	245	0.998	Y = 1.12X + 0.03
APTT (Actin®)	CA-6000	864	0.982	Y = 1.00X – 0.20
APTT (Actin® FS)	CA-6000	857	0.983	Y = 1.00X + 0.10
APTT (Actin® FSL)	CA-6000	864	0.990	Y = 1.00X + 0.10

Summary of Precision Studies
Sysmex® Automated Coagulation Analyzer CA-500

Assay	Control Level	n	Mean	Within Run %CV	Between Run %CV	Total %CV	Max. Error Criteria % CV
PT, Seconds	Control Plasma N	40	11.9	0.7	0.7	0.9	
(Thromborel® S)	Ci-Trol® Level 3	40	59.2	1.1	1.0	1.5	5
PT, INR	Control Plasma N	40	1.1	0.6	0.6	0.8	
(Thromborel® S)	Ci-Trol® Level 3	40	4.6	1.0	0.9	1.3	5
Derived Fibrinogen, g/L	Control Plasma N	40	2.3	1.6	0.6	1.6	
(Thromborel® S)	Path. Plasmapool	40	4.8	1.9	1.7	2.5	10
PT, Seconds	Control Plasma N	40	11.5	0.4	0.2	0.4	
(Dade® Innovin®)	Ci-Trol® Level 3	40	38.0	0.9	1.5	1.8	5
PT, INR	Control Plasma N	40	1.1	0.4	0.2	0.4	
(Dade® Innovin®)	Ci-Trol® Level 3	40	3.7	0.9	1.6	1.8	5
Derived Fibrinogen, g/L	Control Plasma N	40	1.9	2.6	1.4	2.8	
(Dade® Innovin®)	Path. Plasmapool	40	5.2	3.2	1.6	3.4	10
PT, Seconds	Control Plasma N	40	11.5	0.4	0.2	0.4	
(Thromboplastin C Plus)	Ci-Trol® Level 3	40	25.9	1.0	1.5	1.8	5
PT, INR	Control Plasma N	40	1.0	0.7	0.4	0.7	
(Thromboplastin C Plus)	Ci-Trol® Level 3	40	5.0	1.9	3.0	3.5	5
Derived Fibrinogen, g/L	Control Plasma N	40	2.5	1.5	1.3	1.9	
(Thromboplastin C Plus)	Path. Plasmapool	40	5.0	1.6	0.6	1.6	10
APTT	Control Plasma N	40	26.8	1.0	3.4	3.5	
(Dade® Actin)	Ci-Trol® Level 3	40	57.9	0.6	1.3	1.4	5
APTT	Control Plasma N	40	27.1	0.5	0.2	0.5	
(Dade® Actin FS)	Ci-Trol® Level 3	40	63.8	0.3	1.5	1.5	5
APTT	Control Plasma N	40	29.3	0.4	0.2	0.4	
(Dade® Actin® FSL)	Ci-Trol® Level 3	40	61.4	0.4	1.4	1.5	5
D-Dimer	Adv. D-D Control 1	40	5.0	2.4	1.8	2.9	
(Advanced D-Dimer)	Adv. D-D Control 2	40	20.5	1.6	1.4	2.0	15

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP - 8 2003

Mr. Radames Riesgo
Manager, Regulatory Affairs & Compliance
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714

Re: k031377
Trade/Device Name: Sysmex® Automated Coagulation Analyzer CA-500
Regulation Number: 21 CFR 864.5400
Regulation Name: Coagulation instrument
Regulatory Class: Class II
Product Code: GKP
Dated: August 7, 2003
Received: August 8, 2003

Dear Mr. Riesgo:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031377

Device Name: Sysmex® Automated Coagulation Analyzer CA-500

Indications for Use:

The intended use of the Sysmex® CA-500 is as a fully automated, computerized blood plasma coagulation analyzer for *in vitro* diagnostic use in clinical laboratories.

The instrument uses citrated human plasma to perform coagulation tests.

(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 K031377

Prescription Use ✓ **OR** **Over-The-Counter-Use** _____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**