

SEP 30 1998

L981711

Premarket Notification
510(k) Summary of Safety and Effectiveness Information
Sysmex® Automated Coagulation Analyzer CA-500

510K
Summary

Dade Behring Inc.
1851 Delaware Parkway
Miami, FL 33125

Contact Person: Radames Riesgo at 305.636.7727 or by facsimile at 305.637.6887.

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

Common or Usual Name: Automated Coagulation Instruments

Classification Name: Coagulation instrument (21 CFR §864.5400)

Registration Number:

Manufacturing Site

TOA Medical Electronics Co.
Kobe, Japan

7010360

Importer

Sysmex™ Corporation of America
Gilmer Road 6699 RFD
Long Grove, IL 60047-9596

1422681

Distributor

Dade Behring Inc.
1851 Delaware Parkway
Miami, FL 33125

1017272

The CA-500 is substantially equivalent in intended use and technological characteristics to its predecessor, the CA-6000 analyzer. Both instruments are manufactured by TOA Medical Electronics, CO, Ltd., Kobe, Japan. The CA-6000 analyzer was described in details under Document Control No. K964139. The Sysmex® CA-500 is intended for use as an automated blood plasma coagulation analyzer.

Data to support substantial equivalence to the predicate device were generated during correlation studies performed in house. In these studies, comparative performance evaluations were conducted using the proposed device and the predicate device to evaluate specimens from apparently healthy individuals and from patients with different pathological conditions which are

expected to affect the results for a particular assay. The following summary shows the results of the comparison between the proposed and the predicate devices.

**Summary of Method Comparison Studies between
 CA-500 and CA-6000**

Test	Sample Number (n)	Coefficient of Correlation (r)	Regression Equation
Prothrombin Time (Dade® Innovin®, seconds)	111	0.991	$Y = 0.98X + 0.3$
Prothrombin Time (Dade® Innovin®, INR)	111	0.991	$Y = 0.99X + 0.03$
Derived Fibrinogen (Dade® Innovin®)	104	0.983	$Y = 0.78X + 31.2$
Prothrombin Time (Dade® Thromboplastin C Plus, seconds)	131	0.997	$Y = 1.00X + 0.02$
Prothrombin Time (Dade® Thromboplastin C Plus, INR)	131	0.997	$Y = 1.00X + 0.01$
Derived Fibrinogen (Dade® Thromboplastin C Plus)	131	0.979	$Y = 0.92X + 20.2$
Prothrombin Time (Thromborel® S, seconds)	119	0.990	$Y = 0.99X + 0.2$
Prothrombin Time (Thromborel® S, INR)	119	0.989	$Y = 1.00X + 0.01$
Derived Fibrinogen (Thromborel® S)	115	0.985	$Y = 0.86X + 29.2$
Activated Partial Thromboplastin Time (Dade® Actin®)	114	0.997	$Y = 1.00X - 0.3$
Activated Partial Thromboplastin Time (Dade® Actin® FSL)	116	0.997	$Y = 1.01 X - 0.01$
Activated Partial Thromboplastin Time (Pathromtin® SL)	114	0.996	$Y = 0.98X + 1.0$
Fibrinogen (Clauss)	119	0.989	$Y = 0.95X + 20.3$
Thrombin Time	128	0.806	$Y = 0.54X + 9.8$
Antithrombin III	109	0.927	$Y = 0.91X + 10.8$

**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT***
[As Required by 21 CFR 807.87(j)]

*T & A
Statement*

I certify that, in my capacity as manager of Hemostasis Systems Integration of Dade Behring Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

William M. Hoover
William M. Hoover
Manager, Systems Integration

15 May 1998
Date

K981711
Premarket Notification Number

*Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 30 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Radames Riesgo
Manager Regulatory Affairs
DADE Behring, Inc.
P.O. Box 520672
Miami, Florida 33152-0672

Re: K981711/S1
Trade Name: Sysmex® Automated Coagulation Analyzer CA-500
Regulatory Class: II
Product Code: JPA
Dated: September 4, 1998
Received: September 8, 1998

Dear Mr. Riesgo:

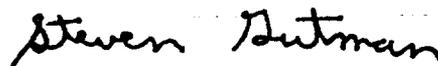
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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" (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/dsma/dsmamain.html>".

Sincerely yours,



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): K981711

*Revis
find to
use*

Device Name: Sysmex® Automated Coagulation Analyzer CA-500

Indications For Use:

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

The instrument uses citrated human plasma to perform the following parameters and calculated parameters:

Clotting Analysis Parameters

- Prothrombin Time (PT)
- Activated Partial Thromboplastin Time (APTT)
- Fibrinogen (Clauss)
- Thrombin Time

Chromogenic Analysis Parameters

- Antithrombin III

Calculated Parameters

- PT Ratio
- PT INR
- Derived Fibrinogen

(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 _____

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)