JUL 20 2001 K011235

510(k) Summary of Safety and Effectiveness Information
Sysmex ® Automated Coagulation Analyzer CA-1500
April 20, 2001

Dade Behring Inc.
13251 NW 9th Terrace
Miami, FL 33182
Contact Person: Radames Riesgo at 305.480.7558 or by facsimile at 305.552.5288.

Trade or Proprietary Name: Sysmex® Automated Coagulation Analyzer CA-1500

Common or Usual Name: Automated Coagulation Instruments

Classification Name: Coagulation instrument (21 CFR §864.5400)

Registration Number:

Manufacturing Site Sysmex Corporation Kobe, Japan	9613959
Importer Sysmex Corporation of America One Wildlife Way Long Grove, IL 60047-9596	1422681
Distributor Dade Behring Inc. Glasgow Site P.O. Box 6101 Newark, DE 19714-6101	2517506

The CA-1500 is substantially equivalent in intended use and technological characteristics to the Behring Coagulation Timer (BCT), Dade Behring, Marburg, Germany which was cleared by FDA under Document Control No. K001064

As demonstrated by clinical correlation studies, the performance claims of the proposed device are similar to the predicate device. During those studies, specimens were evaluated 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 studies between the proposed and the predicate device.

Summary of Method Comparison Studies Between CA-1500 and BCT

Test	Sample Number (n)	Coefficient of Correlation (r)	Regression Equation
D-Dimer Assay	132	0.996	Y = 1.10X – 0.18

Summary of Precision Study Sysmex® Automated Coagulation Analyzer CA-1500

Test	Control Level	n	Mean mg/L (FEU)	Within Run %CV	Between Run %CV	Total %CV	Max. Error Criteria % CV
Advanced D-Dimer	DD1	40	4.3	5.0	1.7	5.0	20
	DD2	40	21.2	5.4	1.9	5.4	
	NP1	40	0.75	12.8	8.0	14.5	

DD1 = Advanced D-Dimer Control Plasma 1
DD2 = Advanced D-Dimer Control Plasma 2
NP1 = Normal plasma pool

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 2 0 2001

Mr. Radames Riesgo
Manager, Regulatory Affairs and Compliance
Dade Behring, Inc.
13251 NW 9th Terrace
Miami, Florida 33182

Re: K011235
Trade Name: Sysmex® Automated Coagulation Analyzer CA-1500
Regulation Number: 21 CFR § 864.5400
Regulatory Class: II
Product Code: JPA
Dated: June 26, 2001
Received: June 27, 2001

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" (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): K011235

Device Name: Sysmex® Automated Coagulation Analyzer CA-1500

Indications for Use:

The intended use of the Sysmex® CA-1500 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 the following parameters and calculated parameters:

Clotting Analysis Parameters

- Prothrombin Time (PT)
- Activated Partial Thromboplastin Time (APTT)
- Fibrinogen (Clauss)
- Batroxobin Time
- Extrinsic Factors (II, V, VII, X)
- Intrinsic Factors (VIII, IX, XI, XII)
- Protein C

Chromogenic Analysis Parameters

- Antithrombin III
- Factor VIII
- Plasminogen
- Heparin
- Protein C
- α2-Antiplasmin

Immunologic Analysis Parameters

- D-Dimer

Calculated Parameters

- PT Ratio
- PT INR
- PT %
- Derived Fibrinogen
- Factor Assays % Activity

(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 K011235

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