DEC - 7 1999

K993299

510(k) Summary of Safety and Effectiveness Information
Sysmex ® Automated Coagulation Analyzer CA-1500
September 30, 1999

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-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 Sysmex® Automated Coagulation Analyzer CA-6000, Sysmex Corporation, Kobe, Japan, which was cleared by FDA under Document Control Nos. K964139 and K992321; or the Behring Coagulation Timer (BCT), Dade Behring, Marburg, Germany which was cleared by FDA under Document Control No. K955278.

As demonstrated by clinical correlation studies, the performance claims of the proposed device are similar to the predicate devices. 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 devices.

Summary of Method Comparison Studies Between CA-1500 and CA-6000 or BCT

Test	Predicate Device	Sample Number (n)	Coefficient of Correlation (r)	Regression Equation
Prothrombin Time (Innovin®, Seconds)	CA-6000	165	0.999	Y = 0.97X + 0.09
Prothrombin Time (Innovin®, INR)	CA-6000	165	0.999	Y = 0.99X + 0.01
Prothrombin Time (Thromborel® S, Seconds)	BCT	163	0.998	Y = 1.04X – 0.51
Prothrombin Time (Thromborel® S, %)	BCT	161	0.996	Y = 1.08X – 2.44
Derived Fibrinogen	BCT	149	0.945	Y = 1.17X – 0.54
Activated Partial Thromboplastin Time	CA-6000	128	0.995	Y = 1.00X + 0.15
Fibrinogen (Clauss)	CA-6000	115	0.985	Y = 0.96X + 0.41
Factor VII	CA-6000	122	0.997	Y = 1.04X – 1.67
Factor VIII	CA-6000	66	0.990	Y = 0.96X + 4.25
Antithrombin III	BCT	104	0.998	Y = 0.97X – 4.72

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

Test	Control Level	N	Mean	Within Run %CV	Between Run %CV	Total %CV
Prothrombin Time	CPN	40	11.5	0.4	0.5	0.6
(Dade® Innovin®, Seconds)	Path. Pool	40	23.3	1.2	0.9	1.4
Prothrombin Time	CPN	40	1.1	0.4	0.5	0.6
(Dade® Innovin®, INR)	Path. Pool	40	2.2	1.2	0.9	1.4
Prothrombin Time	CPN	40	11.8	0.6	2.0	2.1
(Thromborel® S, Seconds)	Path. Pool	40	28.4	0.6	3.0	3.0
Prothrombin Time	CPN	40	95.0	0.9	3.4	3.6
(Thromborel® S, %)	Path. Pool	40	23.4	0.8	4.1	4.2
Derived Fibrinogen	CPN	40	1.8	3.7	3.2	4.7
(Dade® Innovin® on CA-1500)	Path. Pool	40	5.0	2.4	1.2	2.6
Activated Partial Thromboplastin	CPN	40	28.1	2.1	1.4	2.4
Time (Dade® Actin® FSL)	Path. Pool	40	39.5	0.5	1.9	2.0
Fibrinogen (Clauss)	CPN	40	2.7	1.9	2.7	3.2
(Dade® Thrombin Reagent)	CPP	40	0.7	8.4	4.9	9.2
Factor VII	CPN	40	91.6	2.5	1.5	2.7
(Dade® Innovin®)	CPP	40	32.5	2.3	2.1	3.0
Factor VIII	CPN	40	89.1	1.6	3.3	3.6
(Dade® Actin® FSL)	CPP	40	26.0	1.8	4.3	4.6
Antithrombin III	CPN	40	97.4	1.3	4.6	4.8
(Berichrom® Antithrombin III(A))	CPP	40	32.3	2.7	7.6	8.1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC - 7 1999

Mr. Radames Riesgo
Manager, Regulatory Affairs Biology
Dade Behring, Inc.
1851 Delaware Parkway
Miami, Florida 33125

Re: K993299
Trade Name: Sysmex® Automated Coagulation Analyzer CA-1500
Regulatory Class: II
Product Code: GKP
Dated: September 30, 1999
Received: October 1, 1999

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.

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/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): K993299

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)
- Extrinsic Factors (II, V, VII, X)
- Intrinsic Factors (VIII, IX, XI, XII)

Chromogenic Analysis Parameters

- Antithrombin III

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)

Peter E. Maglin

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993299

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