

K964139

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510(k) Summary of Safety and Effectiveness Information
SYSMEX ® Automated Coagulation Analyzer CA-6000
October 11, 1996

Dade International Inc.
9750 N.W. 25 Street
Miami, FL 33172

Contact Person: Radames Riesgo at 305-392-5615 or by facsimile at 305-392-5622.

Trade or Proprietary Name: Sysmex® Automated Coagulation Analyzer CA-6000

Common or Usual Name: Automated Coagulation Instruments

Classification Name: Coagulation instrument (21 CFR §864.5400)

Registration Number:

<i>Manufacturing Site</i>	
TOA Medical Electronics Co.	
Kobe, Japan	7010360
<i>Importer</i>	
Sysmex™ Corporation of America	
Gilmer Road 6699 RFD	
Long Grove, IL 60047-9596	1422681
<i>Distributor</i>	
Dade International Inc.	
9750 N.W. 25 Street	
Miami, FL 33172	1025506

The Sysmex® CA-6000 is substantially equivalent in intended use and technological characteristics to the Electra 1000C™ Automatic Coagulation Timer, manufactured by Medical Laboratory Automation, Inc., Pleasantville, NY, previously cleared under Document Control No., K894052. Sysmex® CA-6000 is intended for use as an automated blood plasma coagulation analyzer.

As demonstrated by in-house 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 devices.

**Summary of Method Comparison Studies between
 CA-6000 and MLA 1000C**

Test	Sample Size (n)	Coefficient of Correlation (r)	Regression Equation
Prothrombin Time (Dade® Innovin®, seconds)	119	0.997	Y= 1.02X + 0.4
Prothrombin Time (Dade® Innovin®, INR)	119	0.997	Y= 1.07X - 0.1
Derived Fibrinogen (Dade® Innovin®)	139	0.988	Y= 1.03X - 6.2
Prothrombin Time (Dade® Thromboplastin C Plus, seconds)	133	0.983	Y= 1.02X - 0.1
Prothrombin Time (Dade® Thromboplastin C Plus, INR)	133	0.984	Y= 1.02X - 0.1
Derived Fibrinogen (Dade® Thromboplastin C Plus)	126	0.992	Y=0.76X +63.9
Activated Partial Thromboplastin Time	128	0.971	Y= 1.00X + 1.7
Fibrinogen (Clauss)	230	0.984	Y= 0.98X -15.0
Thrombin Time	148	0.888	Y= 1.98X - 5.0
Factor VII (Dade® Innovin®)	130	0.987	Y= 0.97X - 2.2
Factor VII (Dade® Thromboplastin C Plus)	131	0.979	Y= 0.94X - 4.4
Factor VIII	118	0.973	Y= 1.04X - 2.2
Antithrombin III	132	0.980	Y= 0.98X + 0.6
Plasminogen	158	0.999	Y= 1.03X - 0.7