

K964946

MAR 18 1997

**ATTACHMENT D**

**510(k) Summary of Safety and Effectiveness  
Information**

**510(k) Summary of Safety and Effectiveness Information**  
**510(k) Additional Information - Premarket Notification**  
**Sysmex® Automated Coagulation Analyzer CA-1000**  
**Sysmex® Automated Coagulation Analyzer CA-5000**  
**December 9, 1996**

Sysmex Corporation of America  
Gilmer Road 6699 RFD  
Long Grove, IL 60047  
Contact Person: Margaret Barranco at (847) 726-3677, or by facsimile at (847) 726-3669.

**Trade or Proprietary Name:** Sysmex® Automated Coagulation Analyzer CA-1000  
Sysmex® Automated Coagulation Analyzer CA-5000

**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

The Sysmex® CA-1000, software version 24 and CA-5000, software version 13 are substantially equivalent to the Sysmex® CA-1000 and CA-5000, K931149/A, K933886, K942096/S1 and K942097/S1, which were originally cleared to market on November 3, 1993 and January 27, 1994, respectively.

Sysmex® CA-1000 & CA-5000 are intended for use as automated blood plasma coagulation analyzers. The systems were described in details in premarket notifications, document control numbers: K931149/A, K933886, K942096/S1 and K942097/S1. The devices belong to the same family of instruments and they are equivalent in their technological features and performance.

The technological characteristics of the predicate device are similar to those previously described for the proposed devices.

In a clinical study, plasma samples with each representative analyte of the core coagulation assays were evaluated by the proposed and the predicate device. This group, which represented approximately even numbers of males and females, consisted of approximately 40 samples.

In this clinical study, the following comparative performance evaluations were conducted using the current and the proposed software versions 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:

**Summary of Method Comparison Evaluations  
 Software Version 21 versus Software Version 24**

Test	Sample Number (n)	Coefficient of Correlation (r)	Regression Equation
Prothrombin Time (PT), seconds	39	0.999	$Y = 0.97X + 0.1$
Activated Partial Thromboplastin Time (APTT), seconds	37	0.978	$Y = 0.99X + 0.7$
Fibrinogen (Clauss), mg/dL	41	0.995	$Y = 0.96X + 10.4$
Derived Fibrinogen	19	0.951	$Y = 1.02X - 9.8$
Factor VII Assay	49	0.996	$Y = 0.95X + 1.0$
Factor VIII Assay	38	0.995	$Y = 0.92X + 0.6$
Thrombin Time	42	0.951	$Y = 1.00X - 0.3$