

K 991101

JUN 1 1999

510(k) Premarket Notification
Organon Teknika Corporation
Coag-A-Mate MAX Coagulation System
510(k) Summary
Organon Teknika Corporation
Coag-A-Mate MAX Coagulation System

- (a)(1) The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;

Submitter's Name: Organon Teknika Corporation

Submitter's Address: 100 Akzo Avenue
Durham, North Carolina 27712

Submitter's Telephone: (919) 620-2288

Submitter's Contact: Rebecca A. Rivas

Date 510(k) Summary Prepared: March 31, 1999

- (a)(2) The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;

Trade or Proprietary Name: Coag-A-Mate MAX Coagulation System
Common or Usual Name: Coagulation System

Classification Name: Coagulation Instrument

- (a)(3) An identification of the legally marketed device to which the submitter claims substantial equivalence;

Device Equivalent to: Organon Teknika MDA- 180
Organon Teknika Coag-A-Mate MTX

- (a)(4) A description of the device.

Device Description: The Coag-A-Mate MAX is a fully automated hemostasis instrument capable of performing coagulation assays that utilize photo-optical detection end point methodology.

- (a)(5) A statement of the intended use of the device.

Device Intended Use: The Coag-A-Mate MAX is a fully automated hemostasis instrument capable of performing coagulation assays that utilize photo-optical detection end point methodology.

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(a)(6) **A summary of the technological characteristics of the new device in comparison to those of the predicate device.**

FEATURES	Coag-A-Mate MAX	MDA – 180	Coag-A-Mate MTX
Photo-Optical Detection	YES	YES	YES
Clotting Assays	YES	YES	YES
Chromogenic Assays	YES	YES	YES
Factor Assays	YES	YES	YES
Calibration	YES	YES	YES
Random Access	YES	YES	YES
User Defineable Parameters	YES	YES	YES
Ancillary Components	Cuvette Racks Pre-Dilution Strips Cleaning Solution Kaolin Suspension Syringe O-Rings Reagent Containers Syringe Plunger Tips	Test Cuvettes Buffer Wash Solution Probe Cleaner Reagent Containers	Test Cuvettes Cleaning Solution Probe Cleaner Reagent Containers
Stat Mode Capability	YES	YES	YES

(b)1) **A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalency.**

Clot Based Assays (Screening)

The PT, APTT and TT assay performance on the CAM MAX is substantially equivalent to the MDA 180. Comparisons were highly correlated (r values of 0.978 to 0.994) in the presence of minimal bias.

Clot Based Assays (Quantitative)

The Fibrinogen, PT Derived Fibrinogen, Factor X and Factor VIII assay performance on the CAM MAX is substantially equivalent to the MDA 180 and / or CAM MTX. Comparisons were highly correlated (r values of 0.976 to 0.993) in the presence of minimal bias. The reportable range for PT Factor X Assay based on the comparison data was established at 4.39% - 158%, values above 93% were extrapolated using a linear least squares regression. The reportable range for APTT Factor VIII Assay based on the comparison data was established at 7.8% - 231.1%, values above 87% were extrapolated using a linear least square regression. The reportable range for Fibrinogen Assay based on the comparison data was established at 110.1 mg/dl – 759.15 mg/dl, values above 494 mg/dl were extrapolated using a linear least square regression. The reportable range for PT Derived Fibrinogen Assay based on the comparison data was established at 131.3 mg/dl – 680.3 mg/dl, values above 494 mg/dl were extrapolated using a linear least square regression.

Colormetric Assays (Chromogenic)

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The Heparin Anti Xa and ATIII assay performance on the CAM MAX is substantially equivalent to the MDA 180. Method comparisons were highly correlated (r value of 0.979 and 0.992) in the presence of minimal bias.

- (b)3) **The conclusions drawn from the testing demonstrating that the device is as safe, as effective, and performed as well or better than the legally marketed device identified in (a)(3).**

The Intended Use and Performance Characteristics of the Coag-A-Mate MAX are comparable to those of the predicate devices and typical of photo-optical coagulation systems in general. Comparison Studies demonstrate equivalence to the MDA-180 and the Coag-A-Mate MTX for the performance of in vitro coagulation studies. For clotting assays correlation coefficients ranged from 0.978 to 0.994, for Factor Assays correlation coefficients ranged from 0.976 to 0.993 and for chromogenic assays correlation coefficients were 0.979 to 0.992.

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TRUTHFUL AND ACCURATE STATEMENT

(As Required by 21 CFR 807.87 (j))

March 31, 1999

I certify that, in my capacity as, Regulatory Affairs Administrator, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.



Rebecca A. Rivas
Organon Teknika Corporation
100 Akzo Avenue
Durham, North Carolina 27712



JUN 1 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Rebecca Rivas
Regulatory Affairs Administrator
Organon Teknika Corporation
100 Akzo Avenue
Durham, N.C. 27712

Re: K991101
Trade Name: Coag-A-Mate® MAX
Regulatory Class: II
Product Code: GKP
Dated: March 31, 1999
Received: April 1, 1999

Dear Ms. Rivas:

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.

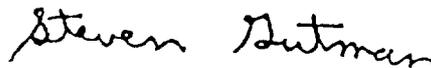
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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 at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/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

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Device Name: Coag-A-Mate® MAX

Indications For Use:

The Coag-A-Mate MAX is a fully automated coagulation system with the capability of performing coagulation assays that utilize photo-optical end point detection methodology. These assays include Screening Assays such as PT, APTT, and TT; Quantitative Clot Based Assays such as Factor VIII and Factor X, Clauss Fibrinogen and Derived PT Fibrinogen; and Colorimetric Assay such as ATIII and Heparin Xa.

Prescription ✓

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED) IF

Concurrence of GDRH, Office of Device Evaluation (ODE)



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

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