

K962857

5.0 510(k) Summary

Coag-A-Mate MTX

JAN 22 1997

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and the final rule under 21 CFR 807.92 published December 14, 1994.

(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

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Submitter's Contact: Ann M. Quinn

Date 510(k) Summary Prepared: July 19, 1996

(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 MTX

Common or Usual Name: Multipurpose System for In Vitro Coagulation Studies

Classification Name: Multipurpose System for In Vitro Coagulation Studies

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

Device Equivalent to: Organon Teknika MDA-180 (K924453)
Organon Teknika Coag-A-Mate X2 (K813564)

(a)(4) A description of the device

Device description: Automated system for in vitro coagulation studies, clot based and chromogenic.

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

Device Intended Use: The Coag-A-Mate MTX is a multipurpose system for use in performing in-vitro coagulation studies, clot based and chromogenic.

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

The CAM MTX, MDA-180 and CAM-X2 are multipurpose systems capable of performing in-vitro coagulation studies, all three perform clot based assays. The MDA-180 and CAM MTX are also capable of performing chromogenic assays.

Similar to the MDA-180, the Coag-A-Mate MTX is a fully automated system that has features which increase its ease of use. Table 1.1 below outlines similarities/differences between the MDA-180 and the CAM MTX.

**Table 1.1
Similarities and Differences Between the MDA-180 and the CAM-MTX**

	MDA-180	CAM-MTX
Spectrophotometric Detection	405 - 710 nm	405 nm
Random Access	yes	yes
Stat Mode Capability	yes	yes
LIS Interface	yes	yes
Assay Capability	Clot Based Chromogenic Immunoassay	Clot Based Chromogenic
Ancillary Components	Imidazole Buffer Reagent Water Wash Solution Probe Cleaner VeriCal Calibrators Test Cuvettes	Probe Cleaner Cleaning Solution Test Cuvettes
User Definable Assay Parameters	yes	yes

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

Testing was performed to determine normal range, correlation and bias, precision and interfering substances. Interfering substances, and specimen collection and preparation are well documented for these types assays and are in accordance with NCCLS standards and recommendations of the International Society of Thrombosis and Hemostasis.

(b)(2) A brief discussion of the clinical tests submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalency.

A comparison study was conducted using patient specimens over the normal, diagnostic and therapeutic range. R values ranged from (0.954 - 0.994) for clot based screening assays, (0.988 - 0.995) for clot based quantitative assays and ($r = 0.954$) for chromogenic assays. Total imprecision for each analyte was well within NCCLS recommendations.

(b)(3) The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performed as well or better than the legally marketed device identified in (a)(3).

The performance characteristics of the new device are comparable to those of the predicate device and typical of these systems in general. The data presented in the premarket notification demonstrate that the new device performs substantially equivalent to the predicate device. Comparison studies were performed to demonstrate the CAM MTX is equivalent to the MDA-180 and CAM-X2 for the performance of in vitro coagulation studies (clotting, chromogenic).

Equivalence was demonstrated using currently commercially available reagents along with patient specimens covering the normal, therapeutic and diagnostic range. Correlation coefficients ranged from $r = 0.954$ to 0.995 for clot based assays. A correlation coefficient of $r = 0.954$ was obtained for assays requiring spectrophotometric measurement at a specified wavelength such as chromogenic assays.

Precision studies were performed following NCCLS EP5-T2 "Evaluation of Precision Performance of Clinical Chemistry Devices." Total precision c.v.'s were less than 5% for clot based screening assays, less than 8% for clot based quantitative assays and less than 7% for colorimetric assays. Data was generated on the CAM MTX using commercially available normal and abnormal control plasma.