K9745566

510(k) Premarket Notification
Organon Teknika Corporation
MDA® Simplastin® HTF

FEB 24 1998

510(k) Summary
MDA®Simplastin® HTF

(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 USA

Submitter's Telephone: (919) 620-2288

Submitter's Contact: Rebecca Rivas

Date 510(k) Summary Prepared: 12/4/97

(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: MDA®Simplastin® HTF

Common or Usual Name: Thromboplastin reagent

Classification Name: Prothrombin time test

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

Device Equivalent to: Ortho RecombiPlasTin® Reagent

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

Device Description: Tissue Thromboplastin reagent for use in determination of the prothrombin (PT) in human plasma.

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

Device Intended Use: Determination of the prothrombin time (PT) in human plasma.

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

Assay Feature	*MDA®Simplastin® HTF*	*Ortho RecombiPlasTin®*
Thromboplastin Source	Cultured Human Cells	Recombinant Human Tissue Factor
Intended Use	Determination of Prothrombin time in human plasma	Determination of Prothrombin time in human plasma
Samples	Anticoagulated Plasma	Anticoagulated Plasma
Technology	Clot formation	Clot formation
Normal Patient Mean(sec.)	12.1 seconds	11.7 second
Preservative	Nitrobromodioxide	Sodium Azide
Controls	Routine Coagulation	Routine Coagulation

(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.**

Testing was performed to establish the performance characteristics of the new device including: Precision studies on three levels of plasma controls, and open vial stability studies.

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

Testing was performed to establish the performance characteristics and substantial equivalence of the new device including: Prothrombin Time method comparison; INR method comparisons; Factor II,V,VII and X method comparison; precision studies on normal plasma pool, borderline abnormal plasma pool and coumadin plasma pool; interference studies on lipemic, icteric and hemolyzed samples; reference ranges on normal plasma pool; and heparin tolerance evaluation utilizing heparin spiked plasma samples.

(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 data shown in this submission supports:

1. The safety and efficacy of MDA® Simplastin® HTF through the following studies: precision studies on controls and clinical specimens, interference studies utilizing clinical specimens, normal donor reference range and open vial stability data.
2. Substantial equivalence to the predicate device Ortho RecombiPlasTin® through the following studies: method comparisons for Prothrombin times, INR values; Factor II; Factor V; Factor VII; and Factor X all utilizing clinical specimens.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 24 1998

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

Re: K974566
MDA® Simplastin® HTF
Regulatory Class: II
Product Code: GJS
Dated: December 4, 1997
Received: December 5, 1997

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 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/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) Premarket Notification
Organon Teknika Corporation
MDA® Simplastin® HTF

510(k) Number (If known): K974566

Device Name: MDA® Simplastin® HTF

Indications For Use:

MDA® Simplastin® HTF is a tissue thromboplastin reagent derived from cultured human cells for use in determination of the prothrombin time (PT) in human plasma.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K974566

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)