UNIVERSAL REAGENTS, INC.
2858 North Pennsylvania Street
Indianapolis, Indiana 46205
PHONE: (317) 926-0015
FAX: (317) 926-0014

K973143

SEP 25 1997

Non-Confidential Summary of Safety and Effectiveness
August 21, 1997

Universal Reagents, Inc.
2858 N. Pennsylvania St.
Indianapolis, IN 46205

Tel - (317) 926-0006
Fax - (317) 926-0014

Official contact: Jorge Miller, Director, Coagulation Products

Proprietary or Trade Name: Factor deficient coagulation plasma - XII

Common/Usual Name: Qualitative and Quantitative Factor Deficiency Test - XII

Classification Name: Qualitative and Quantitative Factor Deficiency Test

Intended device: Factor deficient coagulation plasma - XII

Predicate devices: Pacific Hemostasis Factor XII - K# unknown

Device description: Factor deficient plasma to be free of antigen of Factor XII utilized in *in vitro* diagnostic use.

Intended use:

Indicated use - Factor deficient plasma, Factor - XII is a human plasma immunodepleted of the specific factor and intended for use in the quantitative determination of the specific factor levels in patients suspected of congenital or acquired deficiency of this specific coagulation protein and is performed by clotting assay.

Environment of use: Clinical laboratories

Comparison to predicate devices:

Attribute	**Intended product**	**Pacific Hemostasis**
Use		
Indicated for use in determination of coagulation of plasma	Yes	Yes
In vitro diagnostic use	Yes	Yes
Used as a quantitative assay	Yes	Yes
Design		
Factor XII deficient plasma offered	Yes	Yes

Comparison to predicate devices: (continued)

Attribute	Intended product	Pacific Hemostasis
Packaging either - Frozen or Dry / lyophilized	Yes	Yes
Can be used with different instruments and reagents per manufacturer instructions	Yes	Yes
Materials		
Donor human plasma	Yes	Yes
Various buffers	Yes	Yes
Performance Testing		
Compare assay to known sample	Yes	Yes
Negative by FDA approved test for HIV 1/2 and HBsAG	Yes	Yes
Negative by FDA approved test for HCV and HIV-1ag	Yes	not known
Deficiency of relevant factor less than 1%	Yes	not known
Negative for HIV and HBsAG	Yes	Yes
Negative for HCV, HIV-1ag	Yes	not known
No inhibitors present	Yes	not known

Differences

The only difference is that the intended product is claimed to be negative for HCV and HIV-1ag by an FDA approved test.

Any other differences that do exist would not have a significant effect on the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 25 1997

Jorge Miller
Director, Coagulation Products
Universal Reagents, Inc.
2858 North Pennsylvania Street
Indianapolis, Indiana 46205

Re: K973143
URI Factor XII
Regulatory Class: II
Product Code: GJT, GGP
Dated: September 8, 1997
Received: September 15, 1997

Dear Mr. Miller:

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

C. Indications for Use Statement

Pursuant to the Notice of 2/6/96 regarding listing of Indications for Use on a separate sheet, the following is per that request.

510(k) Number: _____ (to be assigned)

Device Name: Factor Deficient Coagulation Plasma
Factor - XII (12)

Indications for Use:

Indicated use - This product is intended for use in the quantitative determination of factor levels in patients suspected of congenital or acquired deficiency of this coagulation protein or factor, XII.

Factor immunodeficient plasma XII is made from human plasma that has been artificially depleted. This plasma has normal levels of all other factors.

Claims - Negative per FDA approved test for HIV 1/2, HBsAG, HCV, HIV-1ag

Packaging - Frozen
Freeze dried - Lyophilized

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K973143

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