

JAN 13 1999

510(k) Summary for Cryo✓Check™ Factor XI Deficient Plasma1. Submitter's Address and Contact Information

a) Precision Biologicals Incorporated
900 Windmill Rd.
Unit # 100
Dartmouth, Nova Scotia
Canada
B3B 1P7

b) Contact

Mr. Sandy Morrison
Manager, Technical Operations
Phone: (902) 468-6422
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E-mail: pbi@fox.nstn.ca

c) Date Prepared: March 09, 1998

2. Device Name

a) Proprietary (trade) name: Cryo✓Check™ Factor XI Deficient Plasma

b) Common name: Factor XI Deficient Plasma (human)

c) Classification name: Coagulation Factor Deficient Plasma

d) Classification information: Regulatory Class II
Hematology Panel
Product Code - 81 GJT

3. Device Description:

Cryo✓Check™ Factor XI Deficient Plasma is frozen human plasma deficient in the Factor XI coagulation factor. It is prepared from citrated pooled normal human plasma which has been depleted of Factor XI by immunoadsorption. Activity levels of Factor XI are assayed at less than 1% normal levels while all other coagulation factors are within normal ranges.

4. Intended Use

Cryo✓Check™ Factor XI Deficient Plasma is recommended for use as a substrate in clot-based Factor XI assays using the activated partial thromboplastin time (APTT).

5. Substantially Equivalent Device

- a) 510(k) number: K900411
- b)
- c) Trade Name: Factor XI Deficient Plasma
- d) Manufacturer: Sigma
- e) Substantial Equivalence Comparison

Cryo✓Check™ Factor XI Deficient Plasma is similar to the predicate device in that they both have the same “indications for use”; target population; and are both made from human plasma.

Cryo✓Check™ Factor XI Deficient Plasma differs from the predicate device in that it is a frozen liquid preparation and not a lyophilized product. Additionally, **Cryo✓Check™** Factor XI Deficient Plasma is prepared from normal human plasma from which Factor XI has been immunoadsorbed, while the predicate device is derived from human donors with a congenital Factor XI deficiency.

To our knowledge, these differences do not affect the intended use or performance of the device.

6. Non-Clinical Performance Data - 24 Hour Open Vial Stability :

- a) Testing Performed:
 - i) Factor XI assays were performed on a known reference plasma using vials of **Cryo✓Check™** Factor XI Deficient Plasma as a substrate. Recovered factor XI values were measured at 0 hours and 24 hours. (see table for results)
- b) Conclusions:

Test results indicate that a claim of 8 hours open vial stability is acceptable.

Table S1

Open Vial Stability of **Cryo✓Check™**
Factor XI Deficient Plasma

Summary Statistics (% Recovery)

	0 Hours	24 Hours	Average
MEAN	97.2	96.2	96.7
MAXIMUM	99	99	99
MINIMUM	95	93	93
S.D.	1.48	2.28	1.89
2 S.D.	2.97	4.56	3.78
SAMPLE SIZE	5	5	10
C.V.%	1.53	2.37	1.95

Note: Reference Value =
Acceptable values are: Mean (+/-) 5% of reference value; and %C.V. < 5%



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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Sandy Morrison
Manager, Technical Operations
Precision Biologicals Incorporated
900 Windmill Road
Unit # 100
Dartmouth, Nova Scotia
CANADA
B3B 1P7

Re: K981173
Trade Name: Cryo✓ Check™ Factor XI Deficient Plasma
Regulatory Class: II
Product Code: GJT
Dated: March 27, 1998
Received: April 1, 1998

Dear Mr. Morrison:

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 (Pre-market 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.

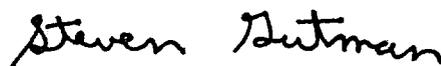
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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

510(k) Number: K981173

Device Name: Cryo✓Check™ Factor XII Deficient Plasma

Indications for Use

Deficiencies in coagulation factors may have congenital or acquired etiologies and can compromise *in vivo* hemostasis. Factor XII (also known as Hageman factor) is a serine protease located in the “intrinsic coagulation pathway”. Patients with Factor XII deficiency generally do not have significant bleeding tendencies. Factor XII deficiency is commonly diagnosed *in vitro* through the use of the activated partial thromboplastin time (APTT).

Cryo✓Check™ Factor XII Deficient Plasma is human plasma deficient in the Factor XII coagulation protein while having all other coagulation factors greater than 50%. It is recommended for use as a substrate in clot-based Factor XII assays using the activated partial thromboplastin time (APTT).



(Division Sign-Off)
Division of Clinical Laboratory Devices K981173
510(k) Number _____

Reception ✓
Use ✓