JUN 1 8 2004

SECTION 6

510(K) Summary
CryoCheck Clot C

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K040987

Submitters Name & Address:	Precision BioLogic Inc. 900 Windmill Road, Suite 100 Dartmouth, Nova Scotia B3B 1P7 Canada
Contact Name:	Stephen L. Duff – Director of New Business Development Phone: 902-468-6422 ext. 224 Fax: 902-468-6421 Email: sduff@precisionbiologic.com
Preparation Date:	April 13, 2004
Device Name & Classification:	CryoCheck Clot C™ Common Name: Clot-based Protein C Assay Classification Name: Test, Qualitative and Quantitative Factor Deficiency Regulatory Class II
Predicate Device:	STA - Staclot Protein C (K861079) Diagnostica Stago 9, rue des Frères Chausson 92600 ASNIERES-SUR-SEINE (France)
Device Description:	CryoCheck Clot C consists of: • Protein C Deficient Plasma – contains citrated pooled normal human plasma that has been depleted of protein C by immunoadsorption. • Clot C Activator – Contains protein isolated from the venom of *Agkistrodon contortrix* capable of activating protein C in human plasma, Russell's viper venom, phospholipids, heparin neutralizing agents, buffers and stabilizers. • CS Diluent (provided separately by Precision BioLogic).
Device Intended Use:	CryoCheck Clot C is a clot-based assay intended for the quantitative determination of protein C activity in citrated human plasma.

Comparison to Predicate Device:

Parameter	CryoCheck Clot C	STA - Staclot Protein C (K861079)
Intended Use	CryoCheck Clot C is a clot-based assay intended for use in the quantitative determination of protein C activity in citrated human plasma.	The STA – Staclot Protein C kit is intended for use with analyzers of the STA brand name, for quantitative measurement of the functional protein C level based on the prolongation of the activated partial thromboplastin time (APTT).
Format	Frozen	Lyophilized
Volume	• 5 x 3.0 mL Protein C Deficient Plasma • 5 x 3.0 mL Clot C Activator OR • 5 x 1.0 mL Protein C Deficient Plasma • 5 x 1.0 mL Clot C Activator	• 3 x 1mL vials of Reagent 1 (Protein C Deficient Plasma) • 3 x 1mL vials of Reagent 2 (PC-Activator).

Correlation with Predicate Device:

CryoCheck Clot C was compared to STA - Staclot Protein C using 119 clinical samples from the target population for the assay. A correlation of R = 0.9142 was obtained.

Comments on Substantial Equivalence:

It is the opinion of Precision BioLogic Inc. that CryoCheck Clot C is substantially equivalent to STA - Staclot Protein C, manufactured by Diagnostica Stago (France), and currently marketed in the United States by Diagnostica Stago Inc. This opinion is based on the following:

- Both products are clot-based assays.
- Both products are intended for use in the quantitative measurement of functional Protein C in citrated human plasma.
- Both products use an extract from the venom of *Agkistrodon contortrix* (Protac®) to activate Protein C in test samples.
- Both products provide all coagulation factors in excess by the use of protein C deficient plasma.

Conclusion:

CryoCheck Clot C is substantially equivalent to STA - Staclot Protein C.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Stephen L. Duff
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Dartmouth, Nova Scotia
Canada B3B 1P7

JUN 1 8 2004

Re: k040987
Trade/Device Name: CryoCheck Clot C
Regulation Number: 21 CFR § 864.7290
Regulation Name: Factor deficiency test
Regulatory Class: II
Product Code: GGP
Dated: April 13, 2004
Received: April 15, 2004

Dear Mr. Duff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040987

Device Name: CryoCheck Clot C

Indications For Use:

CryoCheck Clot C is a clot-based assay intended for the quantitative determination of protein C activity in citrated human plasma.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K 040987