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SECTION 6

510(K) Summary
CRYO*check*™ Clot S™

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: K043571

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:	December 22, 2004
Device Name & Classification:	CRYO*check*™ Clot S™ Common Name: Clot-based Protein S Assay Classification Name: Test, Qualitative and Quantitative Factor Deficiency Regulatory Class II
Predicate Device:	STA® - Staclot® Protein S (K913424) Diagnostica Stago 9, rue des Frères Chausson 92600 ASNIERES (France)
Device Description:	CRYO*check*™ Clot S™ consists of: • Protein S Deficient Plasma – contains citrated pooled normal human plasma that has been depleted of protein S by immunoadsorption, buffers and stabilizers. • Clot S Activator – contains activated protein C, Russell's viper venom, heparin neutralizing agents, buffers and stabilizers. • Precision BioLogic Clot C & S Diluent (available separately from Precision BioLogic).
Device Intended Use:	CRYO*check*™ Clot S™ is a clot-based assay intended for the quantitative determination of protein S activity in citrated human plasma.

Comparison to Predicate Device:

Parameter	CRYO*check*™ Clot S™	STA® - Staclot® Protein S (K913424)
Intended Use	CRYO*check*™ Clot S™ is a clot-based assay intended for use in the quantitative determination of protein S activity in citrated human plasma.	The STA® – Staclot® Protein S kit is intended for use with analyzers of the STA® brand name, for the quantitative measurement of the functional protein S level based on the principle of factor Va inhibition.
Format	Frozen	Lyophilized
Volume	• 5 x 3.0 mL Protein S Deficient Plasma • 5 x 3.0 mL Clot S Activator OR • 5 x 1.5 mL Protein S Deficient Plasma • 5 x 1.5 mL Clot S Activator	• 2 x 1 mL vials of Reagent 1 (Protein S Deficient Plasma • 2 x 1 mL vials of Reagent 2 (Human Activated Protein C) • 2 x 1 mL vials of Reagent 3 (Preparation Containing Bovine Factor Va)

Correlation with Predicate Device:

CRYO*check*™ Clot S™ was compared to STA® - Staclot® Protein S using 115 clinical samples from the target population for the assay. A correlation of R = 0.880 was obtained.

Comments on Substantial Equivalence:

It is the opinion of Precision BioLogic Inc. that CRYO*check*™ Clot S™ is substantially equivalent to STA® - Staclot® Protein S, 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 S in citrated human plasma.
- Both products provide all coagulation factors in excess by the use of protein S deficient plasma.
- Both products use exogenous activated protein C.

Conclusion:

CRYO*check*™ Clot S™ is substantially equivalent to STA® - Staclot® Protein S.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 8 2005

Mr. Stephen L. Duff
Director of New Business Development
Precision BioLogic Inc.
900 Windmill Road, Suite 100
Dartmouth, Nova Scotia
Canada B3B 1P7

Re: k043571
Trade/Device Name: CryoCheck™ Clot S™
Regulation Number: 21 CFR § 864.7290
Regulation Name: Factor deficiency test
Regulatory Class: II
Product Code: GGP
Dated: February 14, 2005
Received: February 15, 2005

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 (240) 276-0484. 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/industry/support/index.html

Sincerely yours,

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

Enclosure

SECTION 5

Indications for Use

510(k) Number: K043571

Device Name: CRYO*check*™ Clot S™

Indications for Use:

CRYO*check*™ Clot S™ is a clot-based assay intended for the quantitative determination of protein S activity in citrated human plasma.

CRYO*check*™ Clot S™ is used to diagnose protein S deficiency (congenital or acquired) which is indicative of an increased risk of thromboembolism. A deficiency in protein S may produce recurrent thrombotic episodes.

Congenital deficiencies of protein S are classified as three types:

- type I deficiencies correspond to reduced antigen levels of both total and free protein S
- type II deficiencies are characterized by a reduced protein S activity but with normal antigen levels of both total and free protein S
- type III deficiencies are defined by a reduced antigen level and activity of free protein S but the antigen level of total protein S remains normal

Acquired protein S deficiencies are associated with several clinical states:

- oral anticoagulant therapy
- liver disease
- disseminated intravascular coagulation
- oral contraceptives
- oestrogen therapy
- acute phase inflammatory responses
- pregnancy
- newborns

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)

Division Sign-Off

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

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K043571