# SECTION 5

## 510(K) Summary
## CRYO*check*™ Clot APCR™

MAY 10 2006

**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:** K060284

### Part A

### 1. Submitter's name, address, telephone, contact person, and the date the summary was prepared

| | |
|---|---|
| **Submitter's Name:** | Precision BioLogic Inc. |
| **Submitter's Address:** | 900 Windmill Road, Suite 100<br>Dartmouth, Nova Scotia B3B 1P7<br>Canada |
| **Submitter's Telephone Number:** | 902-468-6422 |
| **Submitter's Contact Name:** | Stephen L. Duff – Director of New Business Development<br>Phone: 902-468-6422 ext. 224<br>Fax: 902-468-6421<br>Email: sduff@precisionbiologic.com |
| **Date of 510(k) Preparation:** | February 2, 2006 |

### 2. Name of the device, including the trade or proprietary name, the common or usual name and the classification name

| | |
|---|---|
| **Device Name & Classification:** | CRYO*check* Clot APCR |
| **Common Name:** | Activated Protein C Resistance (APCR) Screening Assay |
| **Classification Name:** | Hematology; Test, Time, Partial Thromboplastin<br>Regulatory Class II |

### 3. Identification of the legally marketed device to which the submitter claims substantial equivalence

| | |
|---|---|
| **Predicate Device Name:** | GradiLeiden V<br>510(k) number: K992456<br>Regulation Number: 864.7925<br>Regulatory Class: II<br>Life Therapeutics Ltd.(formerly Gradipore Ltd.)<br>22 Rodborough Road<br>Frenchs Forest, NSW<br>2086 Australia |

## 4. Description of the device

**Device Description:**

CRYO*check* Clot APCR consists of:

- 5 x 2.0 mL Activator Reagent (APC-AR)
- 5 x 4.0 mL Russell's Viper Venom Reagent (APC-RV)

## 5. Statement of the intended use of the device

**Device Intended Use:**

CRYO*check* Clot APCR is a clotting assay intended to screen for resistance to activated protein C in plasma from individuals with the factor $V_{Leiden}$ mutation.

## 6. Summary of the technological characteristics of the new device in comparison to those of the predicate device

### Comparison to Predicate Device:

| Parameter | CRYO*check* Clot APCR | GradiLeiden V - (K992456) |
|---|---|---|
| Intended Use | CRYO*check* Clot APCR is a clotting assay intended to screen for resistance to activated protein C in plasma from individuals with the factor $V_{Leiden}$ mutation. | GradiLeiden V is a simple, functional test system intended for screening of resistance to activated protein C in plasma from individuals with the factor $V_{Leiden}$ defect. |
| Format | Frozen | Lyophilized |
| Volume | • 5 x 2.0 mL Activator Reagent (APC-AR)<br>• 5 x 4.0 mL Russell's Viper Venom Reagent (APC-RV) | • 5 x 2.0 mL Activator Reagent<br>• 5 x 4.0 mL PR3V Reagent |

### Comments on Substantial Equivalence:

It is the opinion of Precision BioLogic Inc. that CRYO*check* Clot APCR is substantially equivalent to GradiLeiden V, manufactured by Life Therapeutics (formerly Gradipore Ltd. Australia), and currently marketed in the United States by Rainbow Scientific. This opinion is based on the following:

- Both products are clot-based assays.
- Both products are intended to screen for resistance to activated protein C in citrated human plasma from individuals with the factor $V_{Leiden}$ defect.
- Both methods rely on the activation of endogenous protein C.
- Both methods perform a dilute Russell's viper venom time (dRVVT) on the plasma with saline and with activator to obtain a ratio which is used for interpretation of a diagnosis.
- Both products can be automated in 2 stage clotting test systems with similar activation and acquisition times.
- Both CRYO*check* Clot APCR and GradiLeiden V tests can be used with the same patient groups.
- Both methods do not require the addition of factor V deficient plasma.

## Part B

### 1. Brief discussion of the non-clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

Non-clinical tests were performed in-house to determine precision, interferences, and stability. CRYO*check* Clot APCR showed comparable precision to that of the predicate, GradiLeiden V. Both devices demonstrated identical results when challenged with interfering substances and factor deficiencies. Storage stability is reflected in product labeling.

### 2. Brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

Clinical tests were performed at Precision BioLogic and a US university hospital-based clinical coagulation laboratory. CRYO*check* Clot APCR and the predicate device exhibited identical sensitivity and specificity.

### 3. Conclusions drawn from the non-clinical and clinical tests that demonstrate that the device is as safe, as effective, and as well or better than the legally marketed device identified in Part A (3)

CRYO*check* Clot APCR and GradiLeiden V have the same intended use and can be used with the same patient groups. Precision BioLogic considers CRYO*check* Clot APCR to be substantially equivalent to GradiLeiden V in terms of intended use, method comparison, and overall performance characteristics. CRYO*check* Clot APCR was compared to GradiLeiden V using 207 clinical samples from the target population for the assay. A correlation of R = 0.960 was obtained.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

MAY 10 2006

Re: k060284
Trade/Device Name: CryoCheck™ Clot APCR™
Regulation Number: 21 CFR § 864.7925
Regulation Name: Partial Thromboplastin Time Tests
Regulatory Class: II
Product Code: GGW
Dated: April 28, 2006
Received: May 2, 2006

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 4

## Indications for Use

**510(k) Number:** K060284

**Device Name:** CRYO*check*™ Clot APCR™

**Indications for Use:**

CRYO*check* Clot APCR is a clotting assay intended to screen for resistance to activated protein C in citrated human plasma from individuals with the factor $V_{Leiden}$ mutation.

| | | | |
|---|---|---|---|
| Prescription Use (Part 21 CFR 801 Subpart D) | ✓ | AND/OR | Over-The-Counter Use (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) K060284