



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Stephen L. Duff  
Precision Biologicals  
900 Windmill Road, #100  
Dartmouth, Nova Scotia  
Canada B3B 1P7

AUG 29 1997

Re: K971219  
Cryo✓Check™ INR Validation Set  
Regulatory Class: II  
Product Code: GGN  
Dated: June 16, 1997  
Received: June 19, 1997

Dear Mr. Duff:

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.

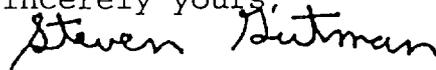
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/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 (if known): not yet issued K# 971219

Device Name: CryoCheck INR Validation Set

Indications For Use: The Prothrombin Time (PT) was first described by Quick and is a common method of monitoring oral anticoagulant treatment in patients receiving warfarin and related drugs. The safety and efficacy of oral anticoagulant therapy is dependent on regular and appropriate laboratory monitoring of the PT test which measures the depression of clotting factors II, VII and X. In 1983 the World Health Organization (WHO) described a scheme for PT standardization based on the International Normalized Ratio (INR). The INR is defined as the Prothrombin Ratio (PR) of the patient raised to the power of the International Sensitivity Index (ISI) of the thromboplastin reagent in use such that  $INR=PR^{ISI}$ .

With the recent proliferation in both commercial thromboplastins and automated coagulation analyzers, the number of PT system combinations has increased significantly. This, in conjunction with the increasing prevalence of the INR reporting system, has resulted in a heightened awareness of variability in test results between laboratories reporting INR's.

CryoCheck INR Validation Set has been designed to enhance the effective monitoring of oral anticoagulant therapy by providing a set of well characterized warfarinized plasmas with system specific INR assigned ranges.

CryoCheck INR Validation Set is indicated for use in monitoring the accuracy and control of oral anticoagulant therapy using the International Normalized Ratio (INR) on a variety of prothrombin time systems. CryoCheck INR Validation Set is not intended for use as calibration or reference plasma and should not be used for calibrating the local International Sensitivity Index (ISI) of commercial thromboplastins.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  (Per 21 CFR 801.109)

OR

Over-The-Counter Use  (Optional Format 1-2-96)

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number 5971219