

**510(k) Summary
HemosIL ProClot**

K070635

Submitted by:

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421

MAR 29 2007

Contact Person:

Carol Marble, Regulatory Affairs Director
Phone No.: 781-861-4467
Fax No.: 781-861-4207

Summary Prepared:

March 22, 2007

Name of the Device:

HemosIL ProClot

Regulatory Information:

864.7290 Factor Deficiency Test Class II
81GGP Test, Qualitative and Quantitative Factor Deficient

Identification of Predicate Device(s):

K912711 HemosIL ProClot

Device Intended Use:

HemosIL ProClot is an automated functional clotting Protein C assay for the quantitative determination of Protein C in human citrated plasma on the IL Coagulation Systems.

Device Description:

The ProClot kit is a functional clotting Protein C test, based on the prolongation of an APTT assay in presence of activated Protein C. The use of the APTT test to measure the anticoagulant effect of activated protein C is due to its sensitivity to FV and FVIII levels. Activated Protein C in plasma samples is generated by Protac[®], a rapid in vitro Protein C activator derived from the venom of the copperhead snake *Agkistrodom contortrix contortrix*.

Reason for Submission:

The Expected Values section of the HemosIL ProClot insert is being modified to reference a normal range from published literature, reinforcing the need for each laboratory to establish its own normal [reference] range due to the many variables which may affect results.

Statement of Technological Characteristics of the Device Compared to Predicate Device:

HemosIL ProClot with the modified Expected Values section in the product insert is not materially different from the FDA cleared device.

Summary of Expected Values Section to the Modified Product Insert:

Protein C activity levels in healthy individuals are approximately in the range of 70 – 140%. Protein C levels are low in neonates and infants and increase to adult levels during adolescence.* Due to many variables which may affect results, each laboratory should establish its own normal range.

* Kottke-Marchant K, Comp P. Laboratory Issues in Diagnosing Abnormalities of Protein C, Thrombomodulin, and Endothelial Cell Protein C Receptor, Arch Pathol Lab med 2002; 126:1337-1348.



INSTRUMENTATION LABORATORY CO.

113 Hartwell Ave.

Lexington, MA 02421

Attn: Carol Marble

MAR 29 2007

Re: k070635

Trade/Device Name: HemosIL ProClot

Regulation Number: 21 CFR 864.7290

Regulation Name: Test, Qualitative and Quantitative Factor Deficiency

Regulatory Class: Class II

Product Code: GGP

Dated: March 06, 2007

Received: March 07, 2007

Dear Ms. Marble:

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.

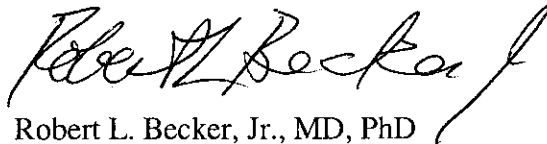
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. 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.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0450. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Robert L. Becker, Jr.", written in a cursive style.

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K070635

Device Name: HemosIL ProClot

Indications for Use:

HemosIL ProClot is an automated functional clotting Protein C assay for the quantitative determination of Protein C in human citrated plasma on the IL Coagulation Systems. Protein C deficiency is associated with recurrent venous thrombosis and pulmonary embolism, especially in young adults. Acquired deficiencies of Protein C are associated with hepatic disorders, oral anticoagulant therapy and disseminated intravascular coagulation.

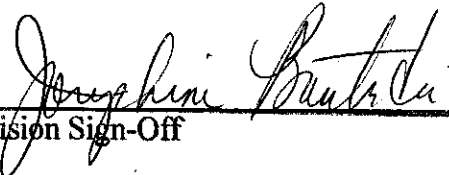
Prescription Use
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
 (21 CFR 801 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) K070635