510(k) Summary
HemosIL Antithrombin

K070301

Submitted by:

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421

FEB 23 2007

Contact Person:

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

Summary Prepared:

January 30, 2007

Name of the Device:

HemosIL Antithrombin

Regulatory Information:

864.7060	Antithrombin III Assay	Class II
81JBQ	Antithrombin III Quantitation	

Identification of Predicate Device(s):

K980499 HemosIL Antithrombin

Device Description:

HemosIL Antithrombin is an *in vitro* diagnostic test for the quantitative determination of Antihrombin in human plasma to monitor the administration of heparin in the treatment of thrombosis and as an aid in the diagnosis of thrombophilia (a congenital deficiency of Antithrombin).

Reason for Submission:

The Expected Values section of the HemosIL Antithrombin 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 Antithrombin 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:

Antithrombin activity levels in healthy individuals are approximately in the range of 83 – 128%. Antithrombin levels are low in neonates/infants and increase to adult levels by approximately 1 year of age; levels are then slightly higher than in adults up to age 16 year.*

Due to many variables which may affect results, each laboratory should establish its own normal range.

* Kottke-Marchant K, Duncan A. Antithrombin Deficiency: Issues in Laboratory Diagnosis, Arch Pathol Lab Med. 2002; 126:1326-1336.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 23 2007

INSTRUMENTATION
LABORATORY
C/O Carol Marble
101 Hartwell Avenue
Lexington, Massachusetts 02421

Re: k070301
Trade/Device Name: HemosIL Antithrombin
Regulation Number: 21 CFR 864.7060
Regulation Name: Antithrombin III Assay
Regulatory Class: Class II
Product Code: JBQ
Dated: January 30, 2007
Received: January 31, 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.

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,

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

cc: HFZ-401 DMC

HFZ-404 510(k) Staff
HFZ- 440 Division
D.O.

Indications for Use Statement

510(k) Number (if known): K070301

Device Name: HemosIL Antithrombin

Indications for Use:

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

(Division Sign-Off) K070301