K033775

JAN - 2 2004

Section 3
HemosIL Liquid Antithrombin XL
510(k) Summary (Summary of Safety and Effectiveness)

Submitted by:

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421

Contact Person:

Carol Marble, Regulatory Affairs Director
Phone: 781-861-4467 / Fax: 781-861-4207

Summary Prepared:

December 2, 2003

Name of the Device:

HemosIL Liquid Antithrombin XL

Classification Name:

864.7060	Antithrombin III Assay	Class II
81JBQ	Antithrombin III Quantitation	

Identification of predicate device:

K980499 HemosIL Antithrombin

Description of the modified device:

HemosIL Liquid Antithrombin XL is a modified version of HemosIL Liquid Antithrombin (K994238) with optimized reagent volumes for use on specific IL Coagulation Systems, such as the ACL Futura (K951891) and ACL Advance (K002400). This modification does not alter the fundamental scientific technology of the device or its intended use as an automated chromogenic assay for the quantitative determination of Antithrombin in human citrated plasma as an aid in the diagnosis of hereditary and acquired Antithrombin deficiency and to monitor Antithrombin substitution therapy.

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

The modified HemosIL Liquid Antithrombin XL is substantially equivalent in performance, intended use, safety and effectiveness to HemosIL Antithrombin (K980499).

Summary of Performance Data:

Within run and between run precision assessed over multiple runs using normal and two abnormal levels of control plasmas gave the results below:

Control Level	n	Mean % AT	Within Run %CV	Between Run %CV
Normal	60	100.85	2.5	3.4
Low Abnormal	60	32.80	4.4	4.9
High Abnormal	60	21.82	6.4	7.4

The following results were obtained in a method comparison study comparing HemosIL Liquid Antithrombin XL to the legally marketed HemosIL Antithrombin (K980499):

n	Slope	Intercept	r	Sample Range
80	1.038	-1.039	0.993	25.4 to 117.1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN - 2 2004

Ms. Carol Marble
Regulatory Affairs Director
Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421

Re: k033775
Trade/Device Name: HemosIL Liquid Antithrombin XL
Regulation Number: 21 CFR 864.7060
Regulation Name: Antithrombin III assay
Regulatory Class: Class II
Product Code: JBQ
Dated: December 2, 2003
Received: December 3, 2003

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 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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
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): K033775

Device Name: HemosIL Liquid Antithrombin XL

Indications for Use:

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This modification does not alter the fundamental scientific technology of the device or its intended use as an automated chromogenic assay for the quantitative determination of Antithrombin in human citrated plasma as an aid in the diagnosis of hereditary and acquired Antithrombin deficiency and to monitor Antithrombin substitution therapy.

For *in vitro* diagnostic use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K033775

Prescription Use X **OR** Over-The-Counter Use _____
(Per 21 CFR 801.019)