K 050544

APR 26 2005

Section 3
HemosIL D-Dimer HS
510(k) Summary (Summary of Safety and Effectiveness)

Applicant Contact Information:

Applicant:	Instrumentation Laboratory Co.
Address:	113 Hartwell Avenue Lexington, MA 02421
Contact Person:	Carol Marble, Regulatory Affairs Director
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Preparation Date: February 28, 2005

Device Trade Name:

HemosIL D-Dimer HS

Regulatory Information:

Classification Name:	Fibrinogen and Fibrin Split Products, Antigen, Antiserum, Control
Device Class:	Class II
Regulation No.:	864.7320
Product Code:	DAP
Panel:	Hematology

Predicate Device:

HemosIL D-Dimer	K972696

Device Intended Use / Description:

HemosIL D-Dimer HS is an automated latex enhanced immunoassay for the quantitative determination of D-Dimer in human citrated plasma on the ACL TOP as an aid in the diagnosis of venous thromboembolism (VTE) [deep venous thrombosis (DVT) and pulmonary embolism (PE)].

The D-Dimer HS Latex Reagent is a suspension of polystyrene latex particles of uniform size coated with the $F(ab')_2$ fragment of a monoclonal antibody highly specific for the D-Dimer domain included in fibrin soluble derivatives. The use of the $F(ab')_2$ fragment allows a more specific D-Dimer detection avoiding the interference of some endogenous factors like the Rheumatoid Factor. When a plasma containing D-Dimer is mixed with the Latex Reagent and the Reaction Buffer included in the D-Dimer HS kit, the coated latex particles agglutinate. The degree of agglutination is directly proportional to the concentration of D-Dimer in the sample and is determined by measuring the decrease of the transmitted light caused by the aggregates (turbidimetric immunoassay).

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

HemosIL D-Dimer HS is substantially equivalent to the commercially available predicate device (HemosIL D-Dimer) in performance and intended use.

Section 3 (Cont.)
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Summary of Performance Data:

Precision

Within run and total precision assessed over multiple runs using three levels of control plasma gave the following results:

ACL TOP:	Mean (ng/mL)	CV% (Within run)	CV% (Total)
D-Dimer Plasma Pool	179.6	8.3	11.0
HemosIL D-Dimer Low Control	313.8	3.7	7.0
HemosIL D-Dimer High Control	677.2	2.0	7.0

Method Comparison

In a method comparison study on an ACL TOP using citrated plasma samples (n=229) ranging in D-Dimer concentration from 87 to 20869 ng/mL, the correlation statistics for HemosIL D-Dimer HS versus the predicate device are shown below:

IL System	Slope	Intercept	r
ACL TOP	0.9492	-50.298	0.973

Management Study

An outcome study was performed on 300 frozen samples from patients admitted consecutively to an emergency unit with suspected PE or DVT (frequency of venous thromboembolic disease: 26%). Of the 300 samples, 78 were confirmed as VTE positive (47 PE and 31 DVT) by standard objective tests and the remaining 222 were confirmed as negative.

Instrument	N	Cut-off	% Sensitivity (95% CI)	% Specificity (95% CI)	% NPV (95% CI)
ACL TOP	300	230 ng/mL	100% (95.4% to 100%)	47% (40.1% to 53.6%)	100% (96.5% to 100%)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 26 2005

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

Re: k050544
Trade/Device Name: HemosIL D-Dimer HS
Regulation Number: 21 CFR § 864.7320
Regulation Name: Fibrinogen and Fibrin Split Products, Antigen, Antiserum, Control
Regulatory Class: II
Product Code: DAP
Dated: February 28, 2005
Received: March 2, 2005

Dear Mr. 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 (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

Indications for Use

510(k) Number (if known): K050544

Device Name: HemosIL D-Dimer HS

Indications for Use:

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For *in vitro* diagnostic use.

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) K050544