K992704

NOV - 1 1999

Section 3
IL Test™ von Willebrand Factor - 510(k) Summary
(Summary of Safety and Effectiveness)

Submitted by:

Instrumentation Laboratory Company
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Contact Person:

Carol Marble, Regulatory Affairs Manager
Phone: 781-861-4467 / Fax: 781-861-4464

Summary Prepared:

August 11, 1999

Name of the Device:

IL Test™ von Willebrand Factor

Classification Name(s):

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

Identification of predicate device(s):

K860371	Asserachrom® vWF

Description of the device/intended use(s):

IL Test™ von Willebrand Factor is an *in vitro* diagnostic automated latex enhanced immunoassay for the quantitative determination of von Willebrand Factor Antigen (vWF:Ag) in human citrated plasma on IL Coagulation Systems. When a plasma containing vWF:Ag is mixed with the Latex Reagent and the Reaction Buffer, the coated latex particles agglutinate. The degree of agglutination is directly proportional to the concentration of vWF:Ag in the sample and is determined by measuring the decrease of transmitted light caused by the aggregates (turbidimetric immunoassay).

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

IL Test™ von Willebrand Factor is substantially equivalent to the commercially available predicate device (Asserachrom® vWF) in performance and intended use.

Section 3
IL Test™ von Willebrand Factor - 510(k) Summary (Cont.)
(Summary of Safety and Effectiveness)

Summary of Performance Data:

In method comparison studies evaluating 120 citrated plasma samples with vWF:Ag levels ranging from 0.3% to 634.3% on an ACL 6000 and an ACL Futura, the slopes and correlation coefficients (r) for IL Test™ von Willebrand Factor versus the predicate device are shown below:

	%vWF:Ag	
IL System	**Slope**	**r**
ACL Futura	1.03	0.997
ACL 6000	1.00	0.996

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

		%vWF:Ag	
	Normal	**Abnormal**	**Abnormal**
ACL Futura	**Level**	**Level I**	**Level II**
Mean	99.50	79.45	35.54
% CV	3.51	2.48	3.16

		%vWF:Ag	
	Normal	**Abnormal**	**Abnormal**
ACL 6000	**Level**	**Level I**	**Level II**
Mean	101.52	80.83	33.67
% CV	1.41	1.25	2.18

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV - 1 1999

Ms. Carol Marble
Regulatory Affairs Manager
Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, Massachusetts 02421

Re: K992704
Trade Name: IL Test™ von Willebrand Fractor
Regulatory Class: II
Product Code: GGP
Dated: August 11, 1999
Received: August 12, 1999

Dear Ms. Marble:

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 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). 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.

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/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

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

Indications for Use Statement

510(k) Number (if known): K992704

Device Name: IL Test™ von Willebrand Factor

Indications for Use:

IL Test™ von Willebrand Factor is an *in vitro* diagnostic automated latex enhanced immunoassay for the quantitative determination of von Willebrand Factor Antigen (vWF:Ag) in human citrated plasma on IL Coagulation Systems. When a plasma containing vWF:Ag is mixed with the Latex Reagent and the Reaction Buffer, the coated latex particles agglutinate. The degree of agglutination is directly proportional to the concentration of vWF:Ag in the sample and is determined by measuring the decrease of transmitted light caused by the aggregates (turbidimetric immunoassay).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter J. Madura

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992704

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