

1K9814179

JUL - 7 1998

Section 3

IL Test™ PT-Fibrinogen Recombinant - 510(k) Summary
(Summary of Safety and Effectiveness)

Submitted by:

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Contact Person:

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Summary Prepared:

April 23, 1998

Name of the Device:

IL Test™ PT-Fibrinogen Recombinant

Classification Name(s):

864.7340	Fibrinogen determination system	Class II
864.7750	Prothrombin time test	Class II
81GIS	Test, fibrinogen	
81GJS	Test, time, prothrombin	

Identification of Predicate Device(s):

K933252/S IL Test™ PT-Fibrinogen HS Plus

Description of the Device/Intended use(s):

IL Test™ PT-Fibrinogen Recombinant permits the *in vitro* diagnostic determination of Prothrombin Time (PT) and Fibrinogen (Fib) in human citrated plasma using a high sensitivity recombinant rabbit tissue factor based thromboplastin. This product is intended for the evaluation of the extrinsic coagulation pathway, monitoring Oral Anticoagulant Therapy (OAT) and for quantitation of fibrinogen.

Statement of how the Technological Characteristics of the Device compare to the Predicate device:

IL Test™ PT-Fibrinogen Recombinant has the same test principle as the predicate IL Test™ PT-Fibrinogen HS Plus and is substantially equivalent in performance, intended use and safety and effectiveness.

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Summary of Performance Data:

In method comparison studies evaluating normal and abnormal plasma samples (n=79) on an ACL 3000 and an ACL Futura, the slopes and correlation coefficients (r) for IL Test™ PT-Fibrinogen Recombinant versus the predicate device are shown below:

System	<u>PT (seconds)</u>		<u>Fibrinogen (mg/dL)</u>	
	Slope	r	Slope	r
ACL 3000	1.04	0.918	0.93	0.977
ACL Futura	1.09	0.949	1.05	0.982

Within run precision assessed over multiple runs using both normal and abnormal samples gave the following results:

ACL 3000	<u>PT (seconds)</u>		<u>Fibrinogen (mg/dL)</u>	
	Normal	Abnormal	Normal	Abnormal
Mean	10.97	24.52	216.04	116.30
% CV	0.53	1.20	4.25	4.36

ACL Futura	<u>PT (seconds)</u>		<u>Fibrinogen (mg/dL)</u>	
	Normal	Abnormal	Normal	Abnormal
Mean	11.98	27.69	261.55	106.11
% CV	1.37	1.99	5.03	2.90



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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Carol Marble
• Senior Regulatory Affairs Specialist
Instrumentation Laboratory Company
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Lexington, Massachusetts 02173-3190

Re: K981479
IL Test PT-Fibrinogen Recombinant
Regulatory Class: II
Product Code: GJS, GIS
Dated: April 23, 1998
Received: April 24, 1998

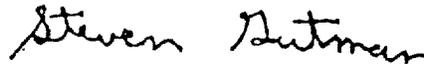
Dear Ms. Marble:

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 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 (Pre-market 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 pre-market 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.

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 "dsmo@fdadr.cdrh.fda.gov".

Sincerely yours,



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): W9 81479

Device Name: IL Test™ PT-Fibrinogen Recombinant

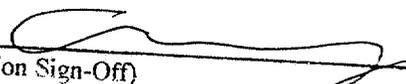
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number W9 81479

Prescription Use
(Per 21 CFR 801.019)

OR Over-The-Counter Use