K973306

SECTION 3
IL Test™ APTT-SP - 510(k) SUMMARY
(Summary of Safety and Effectiveness)

NOV - 4 1997

Submitted by:

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Summary Prepared:

September 2, 1997

Name of the device:

IL Test™ APTT-SP

Classification name(s):

864.7925	Partial Thromboplastin Time Tests	Class II
81 GFO	Activated Partial Thromboplastin	

Identification of predicate device(s):

IL Test™ APTT-C
K881367 for ACL 100, 200, 300 & 300+ Coagulation Analyzers
K871973 for ACL 1000, 2000, 3000 & 3000+ Coagulation Analyzers
K924098 for MCL-2 Coagulation Analyzer
K951891 for ACL Futura
K961991 for ACL 6000 Coagulation Analyzer

Description of the device/intended use(s):

IL Test™ APTT-SP is intended for the *in vitro* diagnostic determination of Activated Partial Thromboplastin Time (APTT) in citrated plasma on IL Coagulation Systems as a general screening procedure for the evaluation of the intrinsic coagulation pathway and to monitor patients receiving heparin anticoagulant therapy.

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

IL Test™ APTT-SP uses the same test principle as the predicate IL Test™ APTT-C and is substantially equivalent in performance, intended use, and safety and effectiveness.

Summary of Performance Data:

In a method comparison study evaluating 73 plasma samples (50 abnormal/23 normal), the correlation (*r*) of the new IL Test™ APTT-SP to the predicate IL Test™ APTT-C on the ACL 300 was 0.915 and on the ACL Futura was 0.907. On the ACL 300, within run precision accessed over multiple runs gave a CV of 0.65% (at a mean of 27.27 seconds), 0.89% (at a mean of 52.05 seconds) and 1.32% (at a mean of 74.65 seconds). On the ACL Futura, within run precision accessed over multiple runs gave a CV of 0.65% (at a mean of 27.50 seconds), 0.84% (at a mean of 50.89 seconds) and 0.93% (at a mean of 72.38 seconds).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Carol Marble
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Instrumentation Laboratory Company
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Lexington, Massachusetts 02173-3190

NOV - 4 1997

Re: K973306
Trade Name: IL Test™ APTT-SP
Regulatory Class: II
Product Code: GFO
Dated: September 2, 1997
Received: September 3, 1997

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 (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 requirement, 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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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): K973306

Device Name: IL Test™ APTT-SP

Indications for Use:

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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 K973306

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