4/8/99

K990302

Section 3

IL Test™ LAC Screen and IL Test™ LAC Confirm (Extension onto the ACL Futura) 510(k) Summary (Summary of Safety and Effectiveness)

Submitted by:

Carol Marble
Regulatory Affairs Manager
Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421
Phone: (781) 861-4467
Fax: (781) 861-4464

Contact Person:

Carol Marble
Phone: (781) 861-4467

Summary Prepared:

January 29, 1999

Name of the device(s):

IL Test™ LAC Screen (extension of reagent onto the ACL Futura)

IL Test™ LAC Confirm (extension of reagent onto the ACL Futura)

Classification name(s):

864.8950 Russell Viper Venom Reagent
81GIR Reagent, Russell Viper Venom

Identification of predicate device(s):

K922156 LUPO-TEST II Reagent (included ACL Series performance data)
K922326 LUCOR Confirmatory Reagent (included ACL Series performance data)

Description of the device/intended use(s):

IL Test™ LAC Screen and IL Test™ LAC Confirm are *in vitro* diagnostic products for the detection of lupus anticoagulants (a type of phospholipid interfering antibody) in human citrated plasma on IL Coagulation Systems. This 510(k) is intended to extend the use of these reagents onto another member in the IL family of coagulation analyzers, the ACL Futura (K951891).

Statement of How the Technological Characteristics of the Device Compare to the Predicate device:

The performance, intended use and safety and effectiveness of IL Test™ LAC Screen (LUPO-Test II) and IL Test™ LAC Confirm (Lucor Confirmatory Reagent) on the ACL Futura Coagulation System is substantially equivalent to that on the ACL Hundred/Thousand Series Coagulation System.

Summary of Performance Data:

In a comparison study of IL Test™ LAC Screen and IL Test™ LAC Confirm on an ACL 300 (reference instrument) versus an ACL Futura (test instrument), the correlation (r) of the normalized LAC ratio was 0.988 (n = 53).

On an ACL Futura, within run precision of IL Test™ LAC Screen and IL Test™ LAC Confirm assessed over multiple runs using 3 levels of plasma gave a CV of 2.52% (at a mean normalized ratio of 0.98), 6.32% (at a mean ratio of 2.03) and 2.36% (at a mean normalized ratio of 1.51).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 8 1999

Ms. Carol Marble
Regulatory Affairs Manager
Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, Massachusetts 02173-3190

Re: K990302
Trade Name: IL Test™ LAC Screen and IL Test™ LAC Confirm on ACL Futura
Regulatory Class: II
Product Code: GIR
Dated: January 29, 1999
Received: February 1, 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): K990302

Device Names: IL Test™ LAC Screen and IL Test™ LAC Confirm
(Extension of Reagents onto the ACL Futura)

Indications for Use:

IL Test™ LAC Screen and IL Test™ LAC Confirm are *in vitro* diagnostic products for the detection of lupus anticoagulants (a type of phospholipid interfering antibody) in human citrated plasma on IL Coagulation Systems. These tests are indicated for use with patients who have prolonged APTT test of undetermined origin.

This 510(k) is intended to extend the use of these reagents onto another member in the IL family of coagulation analyzers, the ACL Futura (K951891).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maksim

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990302

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