K974337

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

DEC 17 1997

Submitted by:

Carol Marble
Regulatory Affairs Engineer
Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02173
Phone: (617) 861-4467
Fax: (617) 861-4464

Contact Persons:

Carol Marble
Phone: (617) 861-4467

Alternate: Betty Lane
Phone: (617) 861-4182

Summary Prepared:

November 17, 1997

Name of the device:

IL Test™ Urea Nitrogen

Classification name(s):

862.1770	Urea Nitrogen test systems	Class II
75CDN	Urease, Photometric, Urea Nitrogen	

Identification of predicate device(s):

IL Test™ Urea Nitrogen	K932467
	K943595 – Serum and Urine Claims Added

Description of the device/intended use(s):

IL Test™ Urea Nitrogen is an *in vitro* diagnostic test for use with Instrumentation Laboratory's line of clinical chemistry systems in the quantitative determination of urea and urea nitrogen in human serum, plasma or urine by enzyme-coupled urease/GLDH methodology. Increases in serum urea nitrogen (urea) can be a result of kidney dysfunction or urinary tract obstruction.

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

The new IL Test™ Urea Nitrogen uses the same methodology as the predicate IL Test™ Urea Nitrogen and is substantially equivalent in performance, intended use, and safety and effectiveness.

Summary of Performance Data:

In a method comparison study evaluating 49 serum samples, the correlation (r) of the new IL Test™ Urea Nitrogen to the predicate IL Test™ Nitrogen was 0.997. In a separate study evaluating 25 urine samples, the correlation (r) of the new IL Test™ Urea Nitrogen to the predicate IL Test™ Urea Nitrogen was 1.000.

Within run precision for a serum sample accessed over multiple runs gave a CV of 2.1 % at a mean of 17 mg/dL and 2.2 % at a mean of 50 mg/dL. Within run precision for a urine sample accessed over multiple runs gave a CV of 2.2 % at a mean of 912 mg/dL.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 17 1997

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

Re: K974337
IL Test™ Urea Nitrogen
Regulatory Class: II
Product Code: CDQ
Dated: November 17, 1997
Received: November 18, 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 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/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

(9)

Indications for Use Statement

510(k) Number (if known): K974337

Device Name: IL Test™ Urea Nitrogen

Indications for Use:

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[1]Friedman, R. et al., Effects of Diseases on Clinical Laboratory Tests, Clin. Chem., 26: (4), 1980

(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 K974334

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