K030215

FEB 2 4 2003

biorapid Mononucleosis - 510(k) Summary
(Summary of Safety and Effectiveness)

Submitted by:

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421
Phone: 781-861-4467
Fax: 781-861-4207

Contact Person:

Carol Marble, Regulatory Affairs Director
Phone: 781-861-4467 / Fax: 781-861-4207

Summary Prepared:

January 17, 2003

Name of the device:

biorapid Mononucleosis

Classification name(s):

866.5640	Infectious Mononucleosis Immunological Test System	Class II
82KTN	System, Test, Infectious Mononucleosis	

Identification of predicate device(s):

K972231	OSOM Mono Test

Description of the Device/Intended Use(s):

biorapid Mononucleosis is a one-step immunoassay for the qualitative detection of infectious mononucleosis heterophile antibodies in whole blood, serum, and plasma samples. The test aids in the diagnosis of infectious mononucleosis.

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

biorapid Mononucleosis uses the same methodology (immunochromatography test) as the predicate OSOM Mono Test and is substantially equivalent in performance, intended use and safety and effectiveness.

Summary of Performance Data:

A total of 622 specimens (296 serum, 261 plasma, and 65 whole blood) were evaluated internally and in an external study with biorapid Mononucleosis and the predicate device, OSOM Mono Test. When compared to the predicate device, biorapid Mononucleosis showed a positive agreement of 100% and a negative agreement of 99.6% (478/480). The overall agreement between the two tests was 99.7%.

A reproducibility evaluation of the biorapid Mononucleosis test was conducted at three physician's offices laboratories (POL's) where testing was performed by personnel with diverse educational backgrounds. At each site, randomly coded samples (three positive and three negative) were tested in triplicate for three days. Results obtained showed a 100% agreement with the expected results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 2 4 2003

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

Re: k030215
Trade/Device Name: biorapid Mononucleosis
Regulation Number: 21 CFR § 866.5640
Regulation Name: Infectious Mononucleosis Immunological Test System
Regulatory Class: II
Product Code: KTN
Dated: January 17, 2003
Received: January 21, 2003

Dear Ms. Marble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K030215

Device Name: biorapid Mononucleosis

Indications for Use:

biorapid Mononucleosis is a one-step immunoassay for the qualitative detection of infectious mononucleosis heterophile antibodies in whole blood, serum, and plasma samples. The test aids in the diagnosis of infectious mononucleosis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

J P Reeves for L. Bautista
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K030215

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