SEP 2 7 2001

K012901

Section 3
Color-Monogen - 510(k) Summary
(Summary of Safety and Effectiveness)

Submitted by:

Instrumentation Laboratory Company
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Contact Person:

Carol Marble, Regulatory Affairs Manager
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Summary Prepared:

August 28, 2001

Name of the device:

Color-Monogen

Classification name(s):

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

Identification of predicate device(s):

K861016 Sure-Vue™ Color Mono

Description of the Device/Intended Use(s):

Simple color-enhanced slide test for the qualitative and semiquantitative detection of infectious mononucleosis heterophile antibodies in serum or EDTA plasma. The test aids in the diagnosis of infectious mononucleosis.

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

Color-Monogen uses the same methodology (direct hemagglutination) as the predicate Sure-Vue™ Color Mono and is substantially equivalent in performance, intended use, and safety and effectiveness.

Summary of Performance Data:

The sensitivity of Color-Monogen was qualitatively tested using 48 samples presumptively positive for IM heterophile antibodies and compared to a commercially available horse red cell slide test. The sensitivity of Color-Monogen relative to the horse red cell slide test was 97.9% (95% Confidence Interval = 88.7 - 99.9%).

The specificity of Color-Monogen was qualitatively tested using 200 randomly selected serum patient samples presumptively negative for IM heterophile antibodies. The specificity of Color-Monogen relative to the horse red cell slide test was 95.8% (95% Confidence Interval = 91.9-98.2%).

In a reproducibility study, an in-house IM heterophile antibody calibrator was diluted from 1/1 to 1/32 and tested by three different operators on 5 consecutive days following the semiquantitative procedure. The color-monogen kit controls (negative and positive) were also tested following the qualitative procedure. Accepting an error on the repeated estimations of only one two-fold dilution, the results indicated that the Color-Monogen semiquantitative and qualitative techniques gave 100% reproducibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 2 7 2001

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

Re: K012901
Trade/Device Name: Color-Monogen
Regulation Number: 21 CFR § 866.5640
Regulation Name: Infectious Immunological Mononucleosis Test System
Regulatory Class: II
Product Code: KTN
Dated: August 28, 2001
Received: August 29, 2001

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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
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): K012901

Device Name: Color-Monogen

Indications for Use:

Simple color-enhanced slide test for the qualitative and semiquantitative detection of infectious mononucleosis heterophile antibodies in serum or EDTA plasma. The test aids in the diagnosis of infectious mononucleosis.

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K012901

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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