DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Interlab, S.R.L.
c/o Mr. Gary Lehnus
Lehnus & Associates Consulting
150 Cherry Lane Road
East Stroudsburg, PA 18301

JUN 30 2006

Re: k053571
Trade/Device Name: Microgel Hemoglobin Test Systems by Electrophoresis
Regulation Number: 21 CFR § 864.7440
Regulation Name: Electrophoretic Hemoglobin Analysis System
Regulatory Class: II
Product Code: JBD
Dated: June 2, 2006
Received: June 5, 2006

Dear Mr. Lehnus:

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 (240) 276-0484. 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/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053571

Device Name: Microgel Hemoglobin Test Systems by Electrophoresis

Indications For Use:

The Microgel Alkaline Hemoglobin Electrophoresis test kit is intended for qualitative and semi-quantitative determination of normal hemoglobins (A1, A2 and F) as well as certain abnormal or variant hemoglobins (S or D and C or E) using agarose gel. To distinguish hemoglobins S from D or C from E an alternate confirmatory test such as acid hemoglobin electrophoresis is necessary. The electrophoretic test is performed at alkaline pH and provides a valuable screening method for hemoglobin patterns. Densitometry of the pattern allows the relative quantification of hemoglobin bands. The kit SRE604K has been designed for use with the fully automated Microgel instrument.

The Microgel Acid Hemoglobin Electrophoresis kit is a qualitative test for the identification of both normal and abnormal or variant hemoglobins, and to confirm the identity of clinically relevant hemoglobins such as A, F, S and C. The Acid Hemoglobin test kit employs agarose gel at acidic pH and is for *in vitro* diagnostic use. The kit has been designed for use with the fully automated Microgel instrument.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K053571