K032862

FEB - 3 2004

510 (k) PREMARKET NOTIFICATION

INTERLAB ALKALINE HEMOGLOBIN ELECTROPHORESIS TEST

(a) **The device name, including the trade name or proprietary name and the common name of the device.**

TRADE NAME: Interlab Alkaline Hemoglobin Electrophoresis test system

COMMON NAME: . Electrophoretic hemoglobin analysis system

(b) **The establishment registration number, if applicable, of the owner or operator submitting the Premarket notification submission.**

InterLab Scientific Instruments srl
Via Rina Monti NN 26 C.A.P. 00155
Rome, ITALY

Establishment Registration Number: 3003961883

Exclusive U.S. Distributor:
ADALTIS
754 Roble Road, Suite 70
Allentown, PA 18109

Establishment Registration Number: 9011134

(c) **The class in which the device has been put under section 513 of the Act and, if known, its appropriate panel; or, if the owner or operator determines that the device has not been classified under this section, a statement of that determination and the basis for the person's determination that the device is not so classified.**

Based upon a review of the Classification of Devices section of 21 CFR, Part 864, Electrophoretic hemoglobin analysis system of the type manufactured by InterLab have been categorized as **Class II** medical devices by the Hematology and Pathology Devices Panel as defined in, **21 CFR 864.7440, Product Code JBD**

(d) **Action taken by the person required registering to comply with the requirements of the Act under section 514 for performance standards.**

This device will comply with all performance standards developed for this type of product.

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STATEMENT OF STAFETY AND EFFECTIVENESS

The sponsor, InterLab srl. has developed, manufactured, and tested under Good Laboratory Practices guidelines, in vitro diagnostic (IVD) devices for semi-quantitative testing of whole blood for the electrophoretic separation of hemoglobin in a screening format. The device trade name is the InterLab Alkaline Hemoglobin Electrophoresis having FDA assigned name: Electrophoretic Hemoglobin Analysis systems, and a classification as a Class II device per 21 CFR Sec. 864.7440, with product code: JBD.

The InterLab Hemoglobin devices test kits for the electrophoretic separation of hemoglobin in whole blood and are intended for *In-Vitro* diagnostic use only. The InterLab Alkaline Hemoglobin Electrophoresis Test Devices provide semi-quantitative identification of hemoglobin bands visualized by staining of the fractions. The principle of hemoglobin electrophoresis is based upon the visualization of specific hemoglobin bands following separation by electrophoresis. Dilutions of a patient's specimen are placed on separate tracks (fingers) on a cellulose acetate slide six fingers shaped, and the major hemoglobin groups are separated by electrophoresis. The migration rate depends on the temperature, pH, ionic force of the solution and proportions of the reactants. After electrophoresis, the slide is processed to remove excess soluble materials through a washing step. Fractionated hemoglobins are stained. The excess of stain is removed by a destaining step.

Studies were performed using 93 samples from both normal and suspected pathological patients submitted for routine testing to the hospital laboratory. The samples were evaluated with the InterLab Hemoglobin test systems (SRE157K and SRE205K) run on the respective Microtech instruments and compared to the laboratory's routine commercially available agarose gel test system following the manufacturers' procedure.

The InterLab Hemoglobin test kits demonstrated equivalent band patterns to the agarose gel test with no false negative or false positive bands observed by visual inspection. This study resulted in a correlation coefficients greater than 0.99 and yielded a 100% agreement to the reference method for the observed bands. These results demonstrate that the InterLab Alkaline Hemoglobin test systems are substantially equivalent to the commercially available reference test. The results of the testing are shown in the tables below.

SRE157K

Hemoglobin Fraction	Slope	y-Intercept	Correlation Coefficient
A1	0.98	1.84	1.00
F	0.97	0.15	1.00
S	0.98	0.34	1.00
A2	1.00	0.08	0.99

SRE205K

Hemoglobin Fraction	Slope	y-Intercept	Correlation Coefficient
A1	1.00	0.19	1.00
F	0.86	1.23	0.99
S	0.92	2.54	1.00
A2	0.99	-0.01	0.99

Analytical Sensitivity

The InterLab Hemoglobin Test systems will detect hemoglobin bands at concentrations greater than 0.40 mg/mL. HbF and HbS samples were serially diluted and run on the InterLab method. The patterns were visually inspected to see when the bands were no longer visible. That sample's dilution was back calculated to determine its concentration.

Precision (Within Slide)

An abnormal control and serum sample were run in replicate on single gel. The patterns were visually inspected and found to be qualitatively identical. In each lane the bands were correctly identified. No false negatives or positives were observed. The following typical results were obtained for the kits.

SRE157K

Hemoglobin Fraction	Mean	SD	CV (%)
A1	35.38	0.32	0.91
F	23.38	0.56	2.38
S	21.91	0.66	3.01
A2	1.99	0.08	4.02
C	19.29	0.56	2.89

SRE205K

Hemoglobin Fraction	Mean	SD	CV (%)
A1	32.81	0.77	2.35
F	25.66	0.62	2.43
S	21.88	0.66	3.04
A2	1.92	0.05	2.60
C	19.65	0.41	2.09

Precision (Slide to Slide)

An abnormal control and a patient sample were run in replicate on multiple separate gels. The patterns were visually inspected and found to be qualitatively identical. In each lane the bands were correctly identified. No false negatives or positives were observed. The following typical results were obtained for the kits.

SRE157K

Hemoglobin Fraction	Mean	SD	CV (%)
A1	36.01	0.57	1.56
F	23.43	0.64	2.74
S	21.54	0.71	3.30
A2	2.00	0.11	5.50
C	19.02	0.48	2.55

SRE205K

Hemoglobin Fraction	Mean	SD	CV
A1	34.22	1.24	3.63
F	23.97	0.64	2.67
S	22.45	0.63	2.82
A2	1.56	0.07	4.48
C	19.35	0.53	2.76

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB - 3 2004

Interlab Scientific Instruments SRL
c/o Mr. Gary Lehnus
Trouble Shooter Consulting, Inc.
150 Cherry Lane Road
East Stroudsburg, PA 18301-8804

Re: k032862
Trade/Device Name: Interlab Alkaline Hemoglobin Test Systems by Electrophoresis
Regulation Number: 21 CFR § 864.7440
Regulation Name: Electrophoretic Hemoglobin Analysis System
Regulatory Class: II
Product Code: JBD
Dated: January 14, 2004
Received: January 23, 2004

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 (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,

Joseph L. Hackett

Joseph L. Hackett, Ph.D.
Acting Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K032862

Device Name: Interlab Alkaline Hemoglobin Test Systems

by Electrophoresis

Indications For Use:

The Interlab Alkaline Hemoglobin Electrophoresis test system is intended for the separation of normal hemoglobins (A1, A2 and F) as well as certain abnormal or variant hemoglobins (S or D and C or E) using cellulose acetate supported on Mylar®. The test is a screening method for in vitro diagnostic use on the Microtech 672 PC and the Microtech 648 ISO fully automated analyzers. To distinguish hemoglobins S from D or C from E an alternate confirmatory test such as acid hemoglobin electrophoresis is necessary.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032862

Prescription Use ✓ OR **Over-The-Counter Use** _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)