ITC

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510 (k) Summary

ITC Hgb Pro Professional Hemoglobin Testing System™

This summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K023561

Prepared: October 21, 2002

Submitted by: John Clay

International Technidyne Corp.
6 Olsen Ave.
Edison, NJ 08820
(732-548-5700) Ext. 265 (732-548-2325) Fax

Device Name

Common / Usual Name: Whole Blood Hemoglobin Test System

Product Name: ITC Hgb Pro Professional Hemoglobin Testing System™

Predicate Device

The Hgb Pro Professional Hemoglobin Testing System™ is substantially equivalent to the a standard clinical laboratory instrument (Coulter MD8) (Beckman Coulter, Inc. Fullerton, CA). The Hgb Pro was also compared to the Hemocue Test System to demonstrate clinical equivalence to another CLIA Waived "point of care" Hemoglobin Test System.

Device Description and Technological Characteristics

The Hgb Pro Professional Hemoglobin Testing System™ consists of a portable, battery operated meter and single-use test strips for the quantitative measurement of total hemoglobin from capillary or venous (EDTA) whole blood. The Hgb Pro Professional Hemoglobin Testing System is designed for near patient testing in a professional facility. The Hgb Pro Professional Hemoglobin Testing System is not intended for home use.

The Hgb Pro meter utilizes optical reflectance for determination of total hemoglobin. The test strip, containing a membrane preloaded with a dried reagent containing a red cell lysing agent, is inserted into the meter. A drop of whole blood is applied to the test location on the strip after a

baseline reading is taken. Blood immediately disperses within the membrane, resulting in lysis of red blood cells and release of hemoglobin. The meter's optical detectors automatically measure the change in membrane reflectance.

The meter calculates and displays the total hemoglobin concentration in grams/deciliter (g/dL; equivalent to percent) or millimole/liter (mmole/L) based on a mathematical conversion table, which is programmed into the instrument. Minor adjustments may be made to the conversion on a lot-by-lot basis based on variation of the raw materials and process to ensure accuracy with the laboratory system. The test result will be displayed in 30 seconds or less.

Statement of Intended Use

The Hgb Pro Professional Hemoglobin Testing System™ consists of a portable, battery operated meter and single-use test strips for the quantitative measurement of total hemoglobin from capillary or venous (EDTA) whole blood. The Hgb Pro Professional Hemoglobin Testing System is designed for near patient testing in a professional facility. The Hgb Pro Professional Hemoglobin Testing System is not intended for home use.

For In Vitro Diagnostic Use Only

Summary of Performance Data, Linearity and Precision

Linearity

The linearity of the Hgb Pro system was tested using one lot of Hgb Pro strips and seven (7) hemoglobin concentrations prepared from a single normal donor. Multiple Hgb Pro instruments (n=5) were tested twice at each concentration. The data were analyzed using the NCCLS guideline EP6-P "Evaluation of the linearity of Quantitative Analytical Methods". The Hgb Pro Hemoglobin Testing System is linear between 4.0 to 24.0 g/dl within 5% of the estimated linear regression line at a 95% confidence level. The linearity regression curve is: Y=0.974x+0.264, r=0.99

Precision studies

The total precision of the Hgb Pro Professional Hemoglobin Testing System was calculated from the testing of commercial controls on multiple days. The Hgb Pro system was tested repeatedly for 20 days with commercially available controls as per NCCLS EP5-T2. The testing for the protocol evaluated three levels of commercial controls (Streck, Para 4®) in four (4) instruments with two lots of Hgb strips. The data in Table 1 was obtained for within run and total precision of the Hgb Pro System.

Table 1	Level I (n=80)		Level II (n=80)		Level III (n=80)	
Precision	Within	Total	Within	Total	Within	Total
Mean	6.86	6.86	11.33	11.33	15.63	15.63
SD	0.17	0.18	0.20	0.25	0.18	0.29
%CV	2.41	2.66	1.73	2.17	1.14	1.86

Additionally, precision of the Hgb Pro system was calculated from testing of freshly prepared whole blood samples created to specified hemoglobin concentrations. Samples were prepared from normal donor blood hemo-diluted or hemo-concentrated to manipulate hgb concentration.

Multiple Hgb Pro instruments were tested repeatedly for 3 days. The hemoglobin levels of the daily-prepared controls were confirmed with the Coulter MD8 Laboratory instrument (Beckman Coulter Inc., Fullerton, CA) and are shown in Table 2 as "Range". Three levels of venous whole blood samples were tested with 5 instruments each day. Over the 3 days, a total of 9 instruments and 3 unique lots of strips were evaluated. Precision across strip lots, instruments and days is shown in Table 2.

Table 2	Level I	Level II	Level III
Range	6.0 - 6.4	13.0 - 13.4	19.4 - 19.9
Mean	6.30	13.44	19.88
SD	0.14	0.32	0.39
%CV	2.25	2.35	1.97
N	87	90	90

Accuracy

Physician Office and Hospital Populations combined, Regression Analysis Summary Hgb Pro and HemoCue Testing Performed in HOSPITAL LAB with VENOUS SAMPLES

Data	Equation	r	n
Hgb Pro vs. HemoCue, all ages combined	y=1.02x - 0.71	0.99	232
Adults only	y=1.01x - 0.62	0.99	162
Neonate / Pediatric	y=1.02x - 0.68	0.99	70
Hgb Pro vs. Coulter, all ages combined	y=1.01x - 0.37	0.99	226
Adults only	y=1.05x - 0.89	0.98	162
Neonate / Pediatric	y=0.99x - 0.25	0.99	64

Hgb Pro and HemoCue tested using FINGERSTICK samples, Coulter tested with venous samples

Data	Equation	r	n
Hgb Pro vs. HemoCue	y=0.78x + 3.01	0.78	87
Hgb Pro vs. Coulter	y=0.96x + 1.18	0.84	87

Conclusion

Clinical validation results demonstrate the Hgb Pro system is substantially equivalent to a standard laboratory instrument Coulter MD-8 and meets the ITC performance requirements specified within the new diagnostic product specifications for the system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 3 1 2003

Mr. John Clay
Director, Regulatory Affairs
International Technidyne Corporation
8 Olsen Avenue
Edison, NJ 08820

Re: k023561
Trade/Device Name: Hgb Pro Professional Hemoglobin Testing System™
Regulation Number: 21 CFR 864.5620
Regulation Name: Automated hemoglobin system
Regulatory Class: Class II
Product Code: GKR
Dated: October 21, 2002
Received: October 23, 2002

Dear Mr. Clay:

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). 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (If Known): K023561

Device Name: Hgb Pro Professional Hemoglobin Testing System™

Indications for Use:

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For In Vitro Diagnostic Use Only

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 801.109

(Optional Format 1-2-96)

Josephine Bartosh

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023561