MAY - 5 2005

K050014

510(k) Summary
for
HemoNIR$_{Lab}$™

1. SPONSOR

NIR Diagnostics Inc.
44 Crawford Crescent
Campbellville, Ontario, L0P 1B0
Canada

Contact Person: Ashwani Kaushal, Vice President, Engineering
Telephone: 905-854-5727

Date Prepared: December 30, 2004

2. DEVICE NAME

Proprietary Name:	HemoNIR$_{Lab}$™
Common/Usual Name:	Whole Blood Hemoglobin Assays
Classification Name:	Oximeter to Measure Hemoglobin

3. PREDICATE DEVICES

- OSM3 Hemoximeter
  Radiometer America, Inc.
  K853990
- AVOXimeter 4000
  A-VOX Sytems, Inc.
  K951485

4. DEVICE DESCRIPTION

HemoNIR$_{Lab}$™ is a small, portable, battery-powered system using rechargeable batteries to measure total hemoglobin, methemoglobin and carboxyhemoglobin using spectroscopic technology. The system uses inexpensive disposable sample tabs and requires no sample preparation or reagents.

Samples are introduced into the HemoNIR$_{Lab}$™ by using sample tabs. The sample tab well is filled with approximately 10uL of sample and is then inserted into the sample slot of the HemoNIR$_{Lab}$™ unit. The unit automatically starts-up and runs its built-in self-test before performing the measurements. After less than 30 seconds from sample insertion, results will be displayed on the built-in LCD.

5. INTENDED USE

HemoNIR$_{Lab}$™ is intended for in vitro diagnostic use by healthcare professionals in quantitative testing of whole blood for total hemoglobin, methemoglobin and carboxyhemoglobin.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The HemoNIR$_{Lab}$™ and the cited predicate devices are all intended for the quantitative measurement of total hemoglobin, methemoglobin and carboxyhemoglobin in samples of anticoagulated whole blood. No sample preparation or reagents are required for either the HemoNIR$_{Lab}$™ or the AVOXimeter 4000, whereas the OSM3 Hemoximeter requires ultrasonic hemolyzation and use of reagents.

Another similarity is that all three devices utilize a spectroscopic measurement method. For the HemoNIR$_{Lab}$™ continuous wavelengths are used while the OSM3 Hemoximeter and AVOXimeter 4000 use six and five wavelengths, respectively. The HemoNIR$_{Lab}$™ is also more compact than the cited predicate devices.

7. PERFORMANCE TESTING

Electrical Testing

The HemoNIR$_{Lab}$™ underwent electrical safety testing and electromagnetic compatibility testing and was found to be in compliance with applicable requirements of IEC 61010-1, IEC 61010-2-101, FCC 47 CFR part 15, and EN 61326.

Performance Testing

Studies were conducted to evaluate the performance characteristics of the HemoNIR$_{Lab}$™. A method comparison study was performed with the HemoNIR$_{Lab}$™ and a commercially available system. Linearity, precision and interference studies were also conducted using the HemoNIR$_{Lab}$™. These studies demonstrated that the HemoNIR$_{Lab}$™ performs in accordance with its specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NIR Diagnostics, Inc.
c/o Ms. Cynthia A. Sinclair, RAC
Senior Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

MAY - 5 2005

Re: k050014
Trade/Device Name: NIR Diagnostics Inc., HemoNIR$_{Lab}$™
Regulation Number: 21 CFR § 862.7500
Regulation Name: Oximeter to measure hemoglobin
Regulatory Class: II
Product Code: JKS, GLY
Dated: April 14, 2005
Received: April 18, 2005

Dear Ms. Sinclair:

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):

Device Name: HemoNIR$_{Lab}$™

Indications for Use:

HemoNIR$_{Lab}$™ is intended for in vitro diagnostic use by healthcare professionals in quantitative testing of whole blood for total hemoglobin, methemoglobin and carboxyhemoglobin.

Prescription Use ___X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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