510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:

K050014

B. Purpose for Submission:

To obtain clearance for the HemoNIR$_{Lab}$™ instrument for the quantitative testing of total hemoglobin, methemoglobin and carboxyhemoglobin.

C. Manufacturer and Instrument Name:

NIR Diagnostics, Inc.

HemoNIR$_{Lab}$™

D. Type of Test or Tests Performed:

Quantitative assay performed by oximeter

E. System Descriptions:

1. 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 HemoNIR$_{Lab}$™ user interface consists of a sample tab receiver, three pushbutton keys, a graphic LCD display and an audible beeper. The HemoNIR$_{Lab}$™ is comprised of the following elements:

- Tungsten lamp for illuminating the sample (wavelength range approximately 450 nm to 850 nm)
- A spectrometer with linear diode array of photo-detectors for measuring the amount of electro-magnetic radiation (EMR) transmitted through the sample
- An electronic board which contains an amplifier, an analog-to-digital converter and a microcontroller for processing the information received by the photodetectors
- Disposable sample tabs and a sample slot in the unit for locating the sample tab
- Primary calibration algorithms for each analyte in each device

2. Principles of Operation:

Samples are introduced in to the HemoNIR$_{Lab}$™ using disposable sample tabs. The sample tab well is filled with sample and then inserted into the HemoNIR$_{Lab}$™ unit's sample slot. The unit automatically starts-up and runs its built-in self-test and then performs a measurement on the sample. The EMR transmitted through the sample is received by the spectrometer/linear diode array and is converted to an analog electronic signal. This signal is proportional to the time that the detector integrates the optical signal. The electronic signal is amplified by analog electronic amplifiers and converted to a digital signal by an analog-to-digital converter.

A reference measurement is taken after a sample measurement, with the sample tab removed, and this is used by the microcontroller to calculate the absorbance. An absorbance calculation is made from the reading of sample and reference light, sample and reference dark and their respective integration times. The algorithm in the unit uses this absorbance to calculate the respective analyte results.

3. Modes of Operation:

The measurement operation is random access.

4. Specimen Identification:

Samples are identified by a unique ID# plus time and date of measurement.

5. Specimen Sampling and Handling:

The HemoNIR$_{Lab}$™ uses disposable, single-use, polypropylene sample tabs that require no sample preparation or reagents. Samples collected in heparin or EDTA is introduced into the HemoNIR$_{Lab}$™ using the sample tabs. The blood sample should be mixed by inverting or rolling it between the fingers (10-20 times) before filling the sample tab well with approximately 10 µL of sample. The snap press-fit cover is closed and it is then inserted into the sample tab receiver on the front of the HemoNIR$_{Lab}$™.

6. Calibration:

The HemoNIR$_{Lab}$™ is factory calibrated and does not require any re-calibration by the user.

7. Quality Control:

To verify that the HemoNIR$_{Lab}$™ is operating within the specification, three QC Optical Filter sample tabs (High, Medium and Low) are supplied with each

HemoNIR$_{Lab}$™ unit with assigned values for Total Hemoglobin.

Additional external controls may be necessary to meet conformance with local, state, and federal regulations or accreditation requirements for quality control.

8. Software:

FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

Yes___X_____ or No_____

The HemoNIR$_{Lab}$™ incorporates embedded software to control several functions of device operation including user interface, self-diagnosis, configuration, measurements and communication.

F. Regulatory Information:

1. Regulation section:

21 CFR 864.7500

2. Classification:

Class II

3 Product code:

GLY

4. Panel:

81 Hematology

G. Intended Use:

1. Indication(s) for Use:

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

2. Special Conditions for Use Statement(s):

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

   (a) OSM3 Hemoximeter (K853990)

   (b) AVOXimeter 4000 (K951485)

2. Comparison with Predicate Device:

Similarities			
Item	Device	Predicate	
	HemoNIR$_{Lab}$™	OSM3 Hemoximeter	AVOXimeter 4000
Intended Use	Quantitative measurement of Total-Hb, Met-Hb & Carboxy-Hb	Same plus other parameters	Same plus other parameters
Sample	Anticoagulated whole blood	Same	Same
Sample preparation	None	Ultrasonic hemolyzation	None
Measurement Method	Spectroscopic	Same	Same
Reagents	No	Yes	No
QC materials	Optical	Aqueous solutions	Optical/aqueous solutions
Battery-Powered	Yes	No	Yes

Differences			
Item	Device	Predicate	
	HemoNIR$_{Lab}$™	OSM3 Hemoximeter	AVOXimeter 4000
Number of wavelengths	Continuous	6	5

I. Special Control/Guidance Document Referenced (if applicable):

Not applicable

J. Performance Characteristics*:*

1. Analytical Performance:

    a. *Accuracy*:

    Accuracy was determined by comparing the results obtained from the HemoNIR$_{Lab}$™ with a predicate device, Radiometer Co-Oximeter OSM 3. In an in-house, single-site study, untreated patient samples obtained from a local hospital, and additional whole blood samples were treated with carbon monoxide and sodium nitrite to obtain elevated levels of carboxyhemoglobin and methemoglobin, respectively.

    Treated samples: Blood samples from 6 normal adult males were treated and aliquotted for a total of approximately 101 independent testing specimens. For each day of testing, a blood sample was obtained from one person in 10 ml heparin or EDTA tubes. The blood was centrifuged and the plasma removed. Met-Hb concentration was increased by reacting the Hb in 1 mL of blood with 100 µL of 10g/L sodium nitrite in phosphate buffered saline (PBS). Carboxy-Hb concentration was increased by reacting the Hb in about 2-4 mL of blood with carbon monoxide (CO) gas in a 10 mL Vacutainer: the air space in the tube was filled with CO and the sample was placed on a rocker for several minutes.

    Untreated samples: A total of 144 samples, 68 male and 76 female adult patients, were obtained from a local hospital with no traceablity to patients. Samples included patients with renal diseases, sickle cell anemia and thalassemia.

    Linear regression analysis was performed for the combined untreated and treated samples. The mean of the summary correlation statistics are as follows:

    Total Hemoglobin: slope = 1.013 and r = 0.980

    Methemoglobin: slope = 0.999 and r = 0.996

    Carboxyhemoglobin: slope = 0.986 and r = 0.982

    An additional study method comparison study was conducted on whole blood samples collected at Milton District Hospital Laboratory, Ontario, Canada. Results from the HemoNIR$_{Lab}$™ were compared to the Radiometer OSM 3

Hemoximeter.

In order to obtain the desired range of abnormal values, approximately half of the whole blood samples were treated with sodium nitrate and carbon monoxide to obtain elevated levels of methemoglobin and carboxyhemoglobin, respectively. Treatment of the samples (as described above) was performed at NIR Diagnostics and the treated samples transported back to the hospital for testing by hospital laboratory personnel.

A total of 109 samples, 51 untreated and 58 treated samples, were tested in parallel on two HemoNIR$_{Lab}$™ units and one Radiometer OSM 3 unit within approximately two minutes.

Linear regression analysis was performed for comparison of the HemoNIR$_{Lab}$™ and Radiometer OSM 3 methods. The mean of the summary correlation statistics are as follows:

Total Hemoglobin: slope = 0.9925 and r = 0.935

Methemoglobin: slope = 1.035 and r = 0.997

Carboxyhemoglobin: slope = 1.014 and r = 0.985

b. Precision/Reproducibility:

A precision study for total hemoglobin was performed to assess the total precision of the HemoNIR$_{Lab}$™ by replicate measurements of quality control materials. Three optical filters representing low, medium and high total hemoglobin concentration levels were used as the quality control materials. Precision studies were performed for 20 days on four HemoNIR$_{Lab}$™ units. Three replicate measurements were performed for each of the three optical filters each day, morning and afternoon.

For each quality control material and each HemoNIR$_{Lab}$™, the mean, standard deviation and % coefficient of variation were calculated. Results demonstrated acceptable measurement precision for total hemoglobin and indicated no systematic error due to drift over the 20 testing days.

Additional precision studies were performed to assess the within-run precision of the methemoglobin and carboxyhemoglobin parameters on the HemoNIR$_{Lab}$™. Human whole blood samples were treated to obtain three concentration levels of methemoglobin and carboxyhemoglobin, respectively. Replicate measurements (20) were run on the HemoNIR$_{Lab}$™, for each sample.

Total Hemoglobin: Mean and % CV for four instruments (average results)

High: Total-Hb = 199.7 g/L, % CV = 3.2

Medium: Total-Hb = 156.5 g/L, % CV = 1.8

High: Total-Hb = 101 g/L, % CV = 3.7

Mean and % CV for within-run precision of methemoglobin and carboxyhemoglobin:

	Methemoglobin			Carboxyhemoglobin		
	Low	Medium	High	Low	Medium	High
Mean	1.6	3.5	35.1	5.9	10.5	19.0
% CV	5.5	6.8	3.7	8.4	7.3	6.1

c. *Linearity*:

Linearity was evaluated by assaying a series of twelve samples, prepared from the whole blood of a single donor that covered a wide range of concentrations. All samples were tested in duplicate on four HemoNIR$_{Lab}$™ units. Results were displayed graphically and examined for linearity by visual inspection. The HemoNIR$_{Lab}$™ demonstrated linearity for the following ranges:

Total Hemoglobin   50-250 g/L

Methemoglobin   0-100 g/L; % Met-Hb is about 2-70% of Total-Hb

Carboxyhemoglobin   0-180 g/L or 0-100% of Total-Hb

d. *Carryover*:

Not applicable

e. *Interfering Substances*:

An interference study was performed to assess the effect of bilirubin, hemolysis, turbidity (Intralipid) and methylene blue on the accuracy of HemoNIR$_{Lab}$™ measurements. A series of samples prepared from whole blood, that included three concentrations of the respective interferent and a baseline sample with no interferent were tested in duplicate on four HemoNIR$_{Lab}$™ units.

Results for samples containing interferents were evaluated relative to samples

in which no interferent was present. The observed differences indicated that there was no effect at interferent levels that would reasonably be expected to occur in clinical situations.

Interference Summary Results: Total-Hb, Met-Hb and Carboxy-Hb

Interferent	Level	Effect
Bilirubin	60 mg/dl	no effect
Hemolysis	2700 mg/dl	no effect
Intralipid	200 mg/dl	no effect
Methylene Blue	50 mg/dl	no effect

"No effect" means the observed bias due to the interferent is less than 20% of baseline. Not applicable to Met-Hb.

2. Other Supportive Instrument Performance Data Not Covered Above:

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.