K090093

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

(As required by 21 CFR 807.92)

Trade Name: HemoPoint® H2 DM Hemoglobin Measurement System

Common/Classification Name: Automated Hemoglobin System

Device Classification: Class: II
CFR: 21 CFR 864.5620
Product Code: GKR

JUN 10 2009

Manufacturer: Stanbio Laboratory
1261 North Main Street
Boerne, Texas 78006

Device Description / Procedure Principle:
The HemoPoint® H2 Hemoglobin Measurement System is comprised of a HemoPoint® H2 Hemoglobin Photometer and HemoPoint® H2 Cuvettes.

The recognized reference method for tHb determination (tHb = total hemoglobin) is the cyanmethemoglobin method, which is also known as the cyanhemoglobin method. The blood sample is diluted 1:251 with a reagent buffering solution. Here the erythrocytes are hemolysed and the bivalent iron in oxy- and desoxyhemoglobin are oxidised by the reagent potassium hexacyanoferrate (III) to trivalent iron and so converted to methemoglobin. Together with cyanide ions, which are also contained in the reagents, the methemoglobin forms a stable, colored complex, namely cyanmethemoglobin. This has a wide absorption maximum at 540 nm. This absorption is proportional to the tHb concentration.

In 1966, Vanzetti suggested to replace KCN by NaN_3 and thus was able to reduce the toxicity of the reagent mixture considerably.

Vanzetti's method is also known as the azide methemogobin method. A modified azide methemoglobin method is used in the HemoPoint® H2 system.

In the *HemoPoint® H2*, however, the use of microcuvettes with short light pathways makes it possible to analyze undiluted blood. The filled cuvette is inserted into the *HemoPoint® H2* photometer, the color produced by the chemical reaction in the cuvette is measured, and the Hb level is calculated and displayed.

In the *HemoPoint® H2* photometer the light transmitted through the cuvette sample is measured.

Principle of photometric transmitted light measurement.

P_0: 100 % - light intensity, P: remaining light intensity, b: distance through the solution

For this purpose, light is directed through the blood sample and the transmission T is measured. From the amount of light absorbed by the sample, the concentration of the hemoglobin in the cuvette can be calculated using Lambert-Beers Law.

Light emitting diodes (LED's) are used as light sources and a photodiode to detect the light. The light emitting diodes utilize the central wavelengths 570 nm (for measurement) and 880 nm (for turbidity compensation).

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS CONT'D

Intended Use:

The HemoPoint H2 Hemoglobin Measurement System is indicated for the quantitative determination of hemoglobin in arterial, venous, or capillary blood.

The microcuvettes part number 3010-100 are indicated for use in the HemoPoint® H2 Hemoglobin Measurement System and compatible measurement systems. The microcuvettes are intended to be used only once and must be disposed of after use as potentially infectious waste.

Estimation of hematocrit as a function of Hemoglobin is performed for normal hemoglobin ranges only (120 to 180 g/L or 12.0 to 18.0 g/dL). The estimated hematocrit is not indicative of disease states such as anemia and abnormal values and will not be reported.

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The DM (Data Management) software modification allows the storage and retrieval of data results along with patient information.

Comparison To Predicate Device: ***(Data presented with K081719 submission)***

Precision:

Within-run imprecision HemoPoint® H2 System and HemoPoint® H2 Cuvettes on HemoCue Device ≤ 2%

	HemoPoint® H2 cuvette measured in HemoPoint® H2 device	**HemoPoint® H2 measured in HemoCue device**
Hemoglobin/high (15.7 g/dL):		
Within-Run Precision (NCCLS EP5-A):	S_{wr} 0.087 g/dL, CV 0.5 %	S_{wr} 0.102 g/dL, CV 0.7 %
Total Precision (NCCLS EP5-A):	S_T 0.1747 g/dL, CV 1.1 %	S_T 0.302 g/dL, CV 1.9 %
Hemoglobin/low (11.8 g/dL)		
Within-Run Precision (NCCLS EP5-A):	S_{wr} 0.070 g/dL, CV 0.6 %	S_{wr} 0.105 g/dL, CV 0.9 %
Total Precision (NCCLS EP5-A):	S_T 0.162 g/dL, CV 1.4 %	S_T 0.198 g/dL, CV 1.6 %
Hemoglobin/normal (8.0 g/dL)		
Within-Run Precision (NCCLS EP5-A):	S_{wr} 0.058 g/dL, CV 0.7 %	S_{wr} 0.068 g/dL, CV 0.8 %
Total Precision (NCCLS EP5-A):	S_T 0.122 g/dL, CV 1.5 %	S_T 0.158 g/dL, CV 1.9 %
Between-Day Imprecision Single observation, 20 days	15.7 g/dL: SD 0.179 g/dL, CV 1.1 % 11.8 g/dL: SD 0.176 g/dL, CV 1.5 % 8.0 g/dL: SD 0.111 g/dL, CV 1.4 %	15.7 g/dL: SD 0.286 g/dL, CV 1.8 % 11.8 g/dL: SD 0.201 g/dL, CV 1.6 % 8.0 g/dL: SD 0.118 g/dL, CV 1.5 %

Correlation Study:

Correlation coefficient HemoPoint® H2 System compared to NCCLS H15-A3 reference method, venous blood: ≥ 0.998

Correlation coefficient HemoPoint® H2 cuvettes on HemoCue Device compared to HemoCue System, venous blood: ≥ 0.995

Experimental Data:

HemoPoint® H2 System: (HemoPoint® H2 cuvettes measured in HemoPoint® H2 device):

Regression line and correlation coefficients compared to NCCLS H15-A3 reference method (g/dL), venous blood (Summary of results)	- Y= 0.2929 + 1.0086X - R=0.999 - N=100, duplicate measurements
Regression line and correlation coefficients compared to HemoCue system (g/dL), venous blood, (Summary of results)	- Y= -5.8261 +1.0462X - R=0.995 - N=100, duplicate measurements

HemoPoint® H2 cuvettes measured in HemoCue device[i]:

Regression line and correlation coefficients compared to HemoCue system (g/dL), venous blood, (Summary of results)	- Y= -0.2181 + 1.0159X - R=0.997 - N=100, duplicate measurements

Comparison to Predicate Device:

Specification	HemoPoint® H2 (Predicate device)	HemoPoint® H2 (New submission)	Comments
Instrument :	No. 1	No. 2	No. 1 ←→ No. 2
Measurement range	0 – 25.6 g/dL	0 – 25.6 g/dL	equivalent
Specified range	0 – 25.6 g/dL	0 – 25.6 g/dL	equivalent
Specified accuracy	± 0.3 g/dL at ≈ 14 g/dL	± 0.3 g/dL at ≈ 14 g/dL	equivalent
Sample material	venous, arterial or capillary human blood	venous, arterial or capillary human blood	equivalent
Measuring time	Approximately 30 – 60 sec	Approximately 30 – 60 sec	equivalent
Measuring units	mol/L, g/dL, g/L	mol/L, g/dL, g/L	equivalent
Calibration	against NCCLS reference method	against NCCLS reference method	equivalent
Method	Azidemethemoglobin method (Vanzetti)	Azidemethemoglobin method (Vanzetti)	equivalent

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS CONT'D

Conclusion / Substantial Equivalence:
The modified software for the HemoPoint® H2 Hemoglobin Photometer and and the predicate devices, Hemo Point® H2 Hemoglobin Measurement System with microcuvette are substantially equivalent based on design and function.

Kirk Johnson
QA/Regulatory Affairs Manager
Stanbio Laboratory

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Stanbio Laboratory
c/o Mr. Kirk Johnson
QA/Regulatory Affairs Manager
1261 North Main Street
Boerne, TX 78006

JUN 10 2009

Re: k090093
Trade/Device Name: HemoPoint® H2 DM Hemoglobin Measurement System
Regulation Number: 21 CFR §864.5620
Regulation Name: Automated Hemoglobin System
Regulatory Class: Class II
Product Code: GKR
Dated: May 27, 2009
Received: May 28, 2009

Dear Mr Johnson:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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

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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090093

Device Name: Stanbio Laboratory HemoPoint® H2 DM Hemoglobin Measurement System

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The HemoPoint H2 Microcuvettes are indicated for use in the HemoPoint® H2 DM Hemoglobin Measurement System. The microcuvettes are intended to be used only once and must be disposed of after use as potentially infectious waste.

Estimation of hematocrit as a function of Hemoglobin is performed for normal hemoglobin ranges only (120 to 180 g/liter or 12.0 to 18.0 g/deciliter). The estimated hematocrit is not indicative of disease states such as anemia and abnormal values will not be reported.

The DM (Data Management) system allows enhanced data management features.

For In Vitro Diagnostic Use Only

Caution: Federal law restricts this device to sale by or on the order of a physician.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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