MAR - 4 2011 K110393

510(k) Summary of Safety and Effectiveness in accordance with 21 CFR 807.92

(a) (1) **Submitted by:**

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Position/Title: Quality Manager

Date of Preparation: January 31, 2011

(2) **Trade Name:** Hemo_Control Hemoglobin Measurement System: Modification to Hemo_Control Microcuvettes

Common/Classification Name: AUTOMATED HEMOGLOBIN SYSTEM

Product Code(s): GKR, 21 CFR §864.5620
KHG, 21 CFR §864.7500

Class: Class II

(3) **Predicate Device(s):** Hemo_Control Hemoglobin Measurement System (K031898) Modification To Stanbio Laboratory Hemopoint H2 Hemoglobin Measurement System (K081719)

Reason for Submission: Device Modification

(4) **Description of Device:**

The Hemo-Control Hemoglobin Measurement System is comprised of a Hemo-Control Hemoglobin Measurement Photometer and Hemo-Control Microcuvettes. The scope of this 510(k) is limited to a modification of the microcuvettes.

The Hemo-Control Microcuvettes are single-use microcuvettes filled with dry reagents. A modified azide methemoglobin method is used. The use of microcuvettes with short light pathways makes it possible to analyze undiluted blood. The filled microcuvette is inserted into the Hemo-Control

Hemoglobin Measurement Photometer, the color produced by the chemical reaction in the microcuvette is measured, and the Hb level is calculated and displayed. Light emitting diodes (LED's) are used as light sources with a photodiode to detect the light.

The plastic microcuvette consists of a clear body with a cavity which takes up approximately 10 µL of blood which combines with the dry reagent chemistry. The optical distance between the microcuvette walls is fixed and permits photometric determination of the hemoglobin in undiluted blood samples using the Lambert-Beers Law. The microcuvette optical and chemical characteristics are unchanged by the modification.

The Hemo_Control Hemoglobin Measurement System with the microcuvette modification employs the identical fundamental scientific technology as the predicate device(s).

(5) **Intended use:**

The intended use, the quantitative determination of hemoglobin in blood, is unchanged by the cuvette modification.

Indications for Use:

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

The microcuvettes part number 3000-3012-0765 are indicated for use in the Hemo-Control 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/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

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(6) **Technological Characteristics:**

The scope of the change in this 510(k) is limited to the microcuvette geometric dimensions. The geometry of the microcuvette is modified for easier filling of the microcuvette and to minimize possible air bubbles forming by implementing a symmetrical sample inlet.

No changes to the Hemo_Control Hemoglobin Measurement System instrument hardware or software are considered in this special 510(k) – no changes to the instrument are required to utilize the modified cuvette.

(b) (1) **Non-Clinical Tests Submitted:**

Changes were evaluated in accordance with the sponsor's Design Control and Risk Management processes. Laboratory testing of the modified cuvettes was performed on venous blood samples per CLSI H15-A3, Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood. A precision evaluation was peformed on 100 samples. The following results were obtained with respect to the reference method:

	HEMO_CONTROL modified microcuvette measured in HEMO_CONTROL device
Hemoglobin/low (8.0 g/dL) Within-Run precision (CLSI EP5-A): Total precision (CLSI EP5-A):	S_{WR} 0.058 g/dL, CV 0.7 % S_T 0.122 g/dL, CV 1.5 %
Hemoglobin/normal (11.8g/dL) Within-Run precision (NCCLS EP5-A): Total precision (NCCLS EP5-A):	S_{WR} 0.070 g/dL, CV 0.6 % S_T 0.162 g/dL, CV 1.4 %
Hemoglobin/high (15.7 g/dL): Within-Run precision (NCCLS EP5-A): Total precision (NCCLS EP5-A):	S_{WR} 0.087 g/dL, CV 0.5 % S_T 0.174 g/dL, CV 1.1 %
Between-Day Imprecision Single observation, 20 days	8.0 g/dL: SD 0.111 g/dL, CV 1.4 % 11.8 g/dL: SD 0.176 g/dL, CV 1.5 % 15.7 g/dL: SD 0.179 g/dL, CV 1.1 %
Regression line and correlation coefficients compared to CLSI H15-A3 reference method (g/dL), venous blood	Y= 0.2929 + 1.0086X R^2=0.9955 N=100, duplicate measurements Range 7.6g/dL to 24.2 g/dL

(2) **Clinical Tests Submitted:** (none)

(3) **Conclusions from Tests:**

As described in (b)(1) above, all of the testing demonstrated that the modified cuvettes number 3000-3012-0765 for the Hemo_Control Hemoglobin Measurement System are substantially equivalent based upon design and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

EKF-diagnostic GmbH
c/o Mr. Stephen Gorski, President
Imagenix, Inc
S65 W35739 Piper Road
Eagle, WI 53119

MAR 0 4 2011

Re: k110393
Trade/Device Name: EKF diagnostic Hemo_Control Hemoglobin Measurement System
Regulation Number: 21 CFR §864.5620
Regulation Name: Automated hemoglobin system
Regulatory Class: Class II
Product Code(s): GKR, KHG
Dated: January 31, 2011
Received: February 11, 2011

Dear Mr. Gorski:

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 class II (Special Controls), 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 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 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

Section 4 - Indications for Use Statement

Indications for Use Statement

510(k) Number: Unknown K110393

Device Name: Hemo-Control Hemoglobin Measurement System

Indications for Use:

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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.

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

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

(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

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