April 06, 2018

EKF-diagnostic GmbH
Mick Fenton
Head of Global QA/RA
Ebendorfer Chaussee 3
39179 Barleben
Germany

Re: K172173
Trade/Device Name: DiaSpect Tm system
Regulation Number: 21 CFR 864.5620
Regulation Name: Automated hemoglobin system
Regulatory Class: Class II
Product Code: GKR
Dated: February 20, 2018
Received: March 05, 2018

Dear Mick Fenton:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR

803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Leonthena R. Carrington -S

Lea Carrington
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172173

Device Name
DiaSpect Tm system

Indications for Use *(Describe)*
The DiaSpect Tm system is intended for the in vitro quantitative measurement of total hemoglobin in non-anticoagulated capillary whole blood and venous whole blood drawn in K2EDTA or lithium heparin tubes. The DiaSpect Tm system consists of the DiaSpect Tm analyzer and specifically designed disposable cuvettes, the DiaSpect Tm Cuvettes. The device is intended for use in point-of-care settings. The DiaSpect Tm analyzer is only to be used with DiaSpect Tm Cuvettes.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5 510(k) Summary

510k Number

K172173

Introduction

In accordance with the requirements of 21CFR807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

I. Submitter

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Date prepared: 10th July 2017

II. Device Name

Proprietary names:	DiaSpect Tm system
Common names:	As above
Classification:	21 CFR 864.5620 – Automated hemoglobin system Class II Hematology Product Code: GKR

III. Predicate Device

The DiaSpect Tm system is substantially equivalent to the currently marketed HemoPoint® H2 Measurement System (K081719).

IV. Device Description

The DiaSpect Tm system consists of an analyzer and cuvettes. The DiaSpect Tm analyzer is a spectrophotometric instrument for the total hemoglobin concentration in unaltered human blood. The DiaSpect Tm Cuvette is injection-molded of poly methyl methacrylate (PMMA) and contains a cavity of 10 µL volume. The cavity is empty.

V. Indications for Use

The DiaSpect Tm system is intended for the in vitro quantitative measurement of total hemoglobin in non-anticoagulated capillary whole blood and venous whole blood drawn in K_2EDTA or lithium heparin tubes. The DiaSpect Tm system consists of the DiaSpect Tm analyzer and specifically designed disposable cuvettes, the DiaSpect Tm Cuvettes. The device is intended for use in point-of-care settings. The DiaSpect Tm analyzer is only to be used with DiaSpect Tm Cuvettes.

Rx only.

VI. Comparison with Predicate

1. Predicate device name(s):
   HemoPoint® H2 Measurement System

2. Predicate 510(k) number(s):
   K081719

Similarities compared to the chosen (FDA cleared; marketed) predicate device (k081719)

Performance	**Predicate Device HemoPoint H2 Measurement System (K081719)**	**Candidate Device DiaSpect Tm system (K172173)**
Indications for use	Determine hemoglobin content of whole blood	Same
Analyte	Hemoglobin	Same
Sample preparation (pre-treatment)	None	Same
Automation	Fully automated assay	Same
Calibration procedure	Factory calibrated	Same
Built in Quality Control	Auto self-check between measurements	same

Differences compared to the chosen (FDA cleared; marketed) predicate device (k081719)

Performance	**Predicate Device HemoPoint H2 Measurement System (K081719)**	**Candidate Device DiaSpect Tm system (K172173)**
Intended Use	The HemoPoint H2 system is intended for the quantitative determination of hemoglobin (Hgb) in whole blood of adults, infants, and children in a professional point-of-care setting. It consists of a dedicated photometer and individual, single-use microcuvettes filled with reagents.	The DiaSpect Tm system is intended for the in vitro quantitative measurement of total hemoglobin in non-anticoagulated capillary whole blood and venous whole blood drawn in K_2EDTA or lithium heparin tubes. The DiaSpect Tm system consists of the DiaSpect Tm analyzer and specifically designed disposable cuvettes, the DiaSpect Tm Cuvettes. The device is intended for use in point-of-care settings. The DiaSpect Tm analyzer is only to be used with DiaSpect Tm Cuvettes. RX only
Method of detection (Test methodology)	Azide methemoglobin	Optical absorbance
Sample type	Capillary, arterial or venous	Capillary or venous
Sample volume	8 µL	< 10µL
Cuvette reagent components	Azide methemoglobin reagent	None
Cuvette storage	15 – 30°C	0 – 50°C
Cuvette components	2 canisters of 50 or 4 canisters of 50	5 packs of 100
Control Kit components	Two concentration levels of controls (3 vials of each)	Three concentration levels of controls (1 vial of each)
Quality Control	Requires two buffer based controls to validate the calibration	Requires three buffer based controls to validate the calibration
Measurement Range	0.0 – 25.6 g/dL	1.2 – 25.5 g/dL
Measuring Time	30-60 seconds	1 second

VII. Performance Characteristics

1. Analytical Performance

a. Precision/Reproducibility:

Precision was determined in accordance with CLSI EP5-A2, "Evaluation of Precision Performance of Quantitative Measurement Methods". Two precision studies were performed at the clinical sites per protocol EKF-PS-01. One study was a 20-Day multi-site study using

three levels of external control material, and the other study was a single-day, single-site precision study with 5 levels of natural and manipulated K2EDTA venous blood.

20-Day Precision

The 20-Day precision was performed by running external controls in duplicate twice per day by two operators at each of three sites (a 20 x 2 x 2 x 3 format with 6 operators, 3 lots, 3 instruments and 3 sites). Lots and instruments were nested with sites. The study was performed by six of the same operators who performed the Method Comparison studies. The 20-Day precision data met the criteria of <7% CV.

20-Day Precision Summary

Sample	***N***	***Mean***	***Within-Run (SD, %CV)***	***Between-Run (SD, %CV)***	***Between-Day (SD, %CV)***	***Between-Operator (SD, %CV)***	***Between-Site (SD, %CV)***	***Total (SD, %CV)***
Level 1	*240*	*7.99*	*(0.085, 1.06%)*	*(0.05, 0.59%)*	*(0.04, 0.47%)*	*(0, 0%)*	*(0.04, 0.45%)*	*(0.11, 1.38%)*
Level 2	*240*	*12.58*	*(0.11, 0.88%)*	*(0.05, 0.38%)*	*(0.03, 0.22%)*	*(0, 0%)*	*(0.06, 0.47%)*	*(0.14, 1.09%)*
Level 3	*240*	*15.82*	*(0.15, 0.92%)*	*(0.06, 0.36%)*	*(0.04, 0.27%)*	*(0, 0%)*	*(0.15, 0.97%)*	*(0.22, 1.41%)*

Single-Day Precision

Single-Day precision was performed at a single site using K_2EDTA venous whole blood. Five donors provided 5 samples, some of which were manipulated by removing plasma to increase hemoglobin, or diluting with the same donor's plasma to decrease hemoglobin. The study was performed at a new single site using 3 instruments, 3 lots and 3 untrained operators who had no prior experience running the DiaSpect Tm, and self-trained on the system. Each of 3 operators ran duplicate tests on all 5 levels with 3 lots of cuvettes in each of 3 instruments, providing 54 measurements for each level. The higher %CV found for Level 5 may be due to the increased viscosity of the abnormally high hematocrit for the samples. The Single-Day precision study met the criteria of <7% CV.

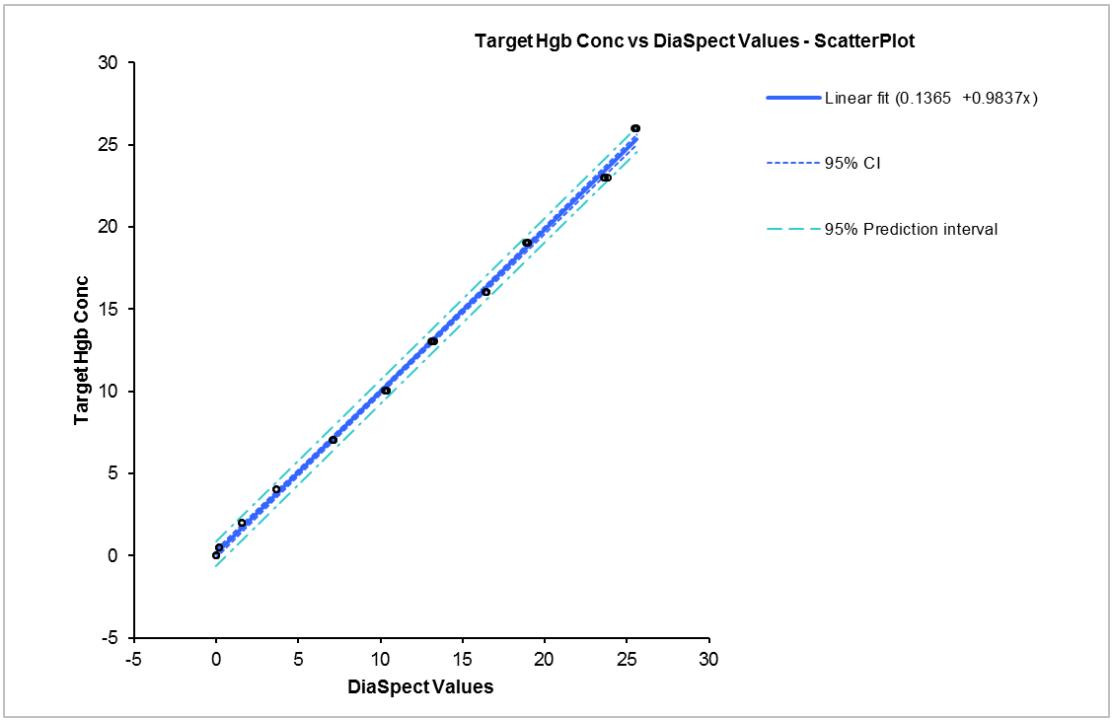
Single-Day Precision Summary

Sample	***N***	***Mean***	***Within-Run (SD, %CV)***	***Between-lot (SD, %CV)***	***Between-Operator (SD, %CV)***	***Between-Analyzer (SD, %CV)***	***Total (SD, %CV)***
Level 1	*54*	*4.87*	*(0.05, 0.97%)*	*(0.04, 0.82%)*	*(0.02, 0.42%)*	*(0.11, 2.19%)*	*(0.13, 2.57%)*
Level 2	*54*	*10.19*	*(0.19, 1.87%)*	*(0, 0%)*	*(0.06, 0.6%)*	*(0.12, 1.17%)*	*(0.23, 2.29%)*
Level 3	*54*	*13.75*	*(0.38, 2.77%)*	*(0.07, 0.48%)*	*(0.21, 1.5%)*	*(0, 0%)*	*(0.44, 3.19%)*

Level 4	*54*	*17.46*	*(0.69, 3.93%)*	*(0, 0%)*	*(0.08, 0.48%)*	*(0.37, 2.14%)*	*(0.79, 4.5%)*
Level 5	*54*	*22.93*	*(1.45, 6.33%)*	*(0, 0%)*	*(0.3, 1.32%)*	*(0, 0%)*	*(1.48, 6.47%)*

b. Linearity

A linearity study was conducted based on CLSI EP6-A. Specimens having eleven hemoglobin levels were prepared from venous whole blood. Each level was tested in triplicate on one DiaSpect Tm analyzer. Average results were plotted against results obtained from a HemoPoint® H2 analyzer, which was used as the reference method. Summarized results are presented in the following diagram. The correlation coefficient was greater than 0.95 and the slope of the linear equation was within 1.0±0.1 which met acceptance criteria.



d. Detection Limit:

<u>LoB</u>

Plasma samples were obtained from (5) individual whole blood donors. The five (5) plasma "blank" samples were tested for 3 days on one (1) DiaSpect Tm meter in quadruplicate (x4) using two (2) different lots of DiaSpect Tm cuvettes.

<u>LoD</u>

Four (4) whole blood samples (K_2EDTA) were collected from different donors. Four (4) independent samples covering Hgb concentrations 0.1 to 0.4 g/dL were prepared. Each sample was tested sixty (60) times on (1) DiaSpect Tm device using two (2) different lots of DiaSpect Tm cuvettes for 3 days.

LoQ

Nine (9) unique donor whole blood samples were used to prepare concentrations from 0.7-1.5 g/dL. Each sample was tested using two lots of DiaSpect Tm cuvettes on one DiaSpect Tm analyzer at least ten times for each lot for three days to achieve variability. The mean and SD for each sample concentration for each cuvette lot was determined and the bias for each of the nine levels calculated. LoQ was determined from the specified Total Error to be 1.2g\dL.

Sensitivity	Concentration
LoB	0.0 g/dL
LoD	0.3 g/dL
LoQ	1.2 g/dL

e. Analytical specificity:

Interference and cross-reactivity studies were performed in accordance with the CLSI guidance EP7-A2 "Interference testing in clinical chemistry".

Whole venous blood was collected with K_2EDTA tubes and was manipulated to create 3 hemoglobin concentrations of 11.0, 14.0, and 18.0 g/dL. Each hemoglobin concentration was spiked with potential interferent at the test concentrations listed below.

For Disease Conditions K_2EDTA venous blood specimens from up to five (5) donors with the following conditions were collected: Polycythemia, Hypochromia, High WBC Count and Sickle Cell. The predicate device HemoPoint(H2) was used as the reference method to obtain the Hgb concentration. Each sample was tested in duplicate on the H2 and five times on the DiaSpect Tm device. The predicate HemoPoint(H2) average was used to calculate the bias against each individual DiaSpect Tm result.

Potential interferent	Test Concentration	Design acceptance criteria	Result
Bilirubin	20.0 mg/dL	$\leq$ 7%	Passed
Cholesterol	500 mg/dL	$\leq$ 7%	Passed
Creatinine	5 mg/dL	$\leq$ 7%	Passed
Protein	12 mg/dL	$\leq$ 7%	Passed
Triglyceride	1000 mg/dL	$\leq$ 7%	Passed
Urea	258 mg/dL	$\leq$ 7%	Passed
Uric Acid	24 mg/dL	$\leq$ 7%	Passed
Acetaminophen	2 mg/dL	$\leq$ 7%	Passed
Ascorbic Acid	6 mg/dL	$\leq$ 7%	Passed
Dopamine	0.1 mg/dL	$\leq$ 7%	Passed
Ibuprofen	55 mg/dL	$\leq$ 7%	Passed
Tetracycline	1.5 mg/dL	$\leq$ 7%	Passed
Ferrous Sulfate	22 mg/dL	$\leq$ 7%	Passed
Ammonium Ferric Citrate	30 mg/dL	$\leq$ 7%	Passed
Ferrous Fumarate	30 mg/dL	$\leq$ 7%	Passed

Iron Dextran	284 mg/dL	≤ 7%	Passed
Folic Acid	1000 ng/mL	≤ 7%	Passed
Vitamin B12	2500 ng/mL	≤ 7%	Passed
Lithium Carbonate	23 mg/dL	≤ 7%	Passed
Immunoglobin	500 mg/dL	≤ 7%	Passed
Methyldopa	1.7 mg/dL	≤ 7%	Passed
Salicylic Acid	100 mg/dL	≤ 7%	Passed
5x EDTA	Tube filled to 1/5 volume	≤ 7%	Passed
Hypochromia	Disease state	≤ 7%	Passed
High WBC Count	Disease state	≤ 7%	Passed
Polycythemia	Disease state	≤ 7%	Passed
Sickle Cell	Disease state	≤ 7%	Passed

All potential interferants tested within the acceptance criteria.

f. Assay cut-off:

Not applicable

g. Stability

Cuvettes from 12 different lots produced between December 2008 and July 2011 were tested in July 2011. Four cuvettes from each lot were tested by measuring the medium level of the DiaSpect Control HB, target value 12.6 g/dL, on the DiaSpect device.

The mean value of the measurements from all lots is 12.59 g/dL, with a total CV 0.75%. The results of measurements are summarized in the following Table.

Cuvette Lot	Production Date	Mean Hb g/dL
D080205	2008-12-18	12.53
D090001	2009-01-20	12.40
D090002	2009-05-26	12.50
D090007	2009-08-31	12.50
D090020	2009-12-08	12.60
D100009	2010-03-31	12.70
D100019	2010-05-03	12.65
D100034	2010-08-05	12.70
D100045	2010-11-28	12.60
D110007	2011-02-28	12.58
D110013	2011-05-02	12.70
D110022	2011-07-11	12.60
Mean Hb g/dL		12.59

SD	0.09
CV %	0.75
Min - Max, Hb g/dL	12.4 - 12.7

Conclusion: The DiaSpect Tm cuvette has a shelf life of at least 2.5 years.

h. Calibration

The DiaSpect Tm analyzer is factory calibrated and is not user adjustable.

i. Quality Control

The DiaSpect Tm system includes 3 levels of control solutions with known hemoglobin concentration. The DiaSpect Control HBT is produced in three concentrations that correspond to three levels of human hemoglobin. Each vial contains 1.9 mL of a solution of a red dye (Rhodamine) in purified water. The reagent does not contain any material of human or animal origin.

The DiaSpect Control HBT is 510(k) exempt.

2. Method Comparison Studies

Method comparison:

Method comparison studies were performed across four sites to support the substantial equivalence of the DiaSpect Tm Hemoglobin System with the predicate device. Finger stick capillary, K_2EDTA and lithium heparin venous whole blood specimens from a total of 399 subjects across four point-of-care clinical sites were tested on-site with both the DiaSpect Tm system (in singlicate) and in the HemoPoint® H2 Hemoglobin Analyzer (comparative method, in duplicate). IRB approval was obtained prior to initiating the studies.

A total of 364 male and female subjects, ranging from 9 months to 89 years of age, provided 363 capillary samples ranging from 8.5 to 20.1 g/dL, 349 EDTA venous samples ranging from 6.5 to 19.9 g/dL and 120 heparin venous samples ranging from 10.4 to 20.0 g/dL when tested in the DiaSpect Tm system. An additional 35 contrived EDTA venous samples were divided between three sites and tested to challenge the full measuring range of the DiaSpect Tm system. Of the 349 EDTA venous samples, five samples with hemoglobin values of 6–7 g/dL were tested in comparison with the predicate at one additional internal site to demonstrate the performance of the device around these levels.

Testing was performed over a 5-week period by 9 operators using four DiaSpect Tm analyzers and three lots of DiaSpect Tm Cuvettes. A single lot of tri-level DiaSpect Control HBT external controls were run each day specimens were tested. Clinical Study sites were required to have a current Certificate of Waiver and all operators were untrained, intended use operators. Operators were full time employees of the Certificate of Waiver test sites used in the study, who normally perform phlebotomy and/or participate in patient testing. Capillary whole blood and K_2EDTA venous whole blood were tested at the four sites by 9 operators. Lithium heparin was tested at one site by two operators. The results for all natural and contrived samples combined are summarized in Table below.

Table Overall Results Summary, Natural and Contrived, Samples All Sites

Site #	Blood Type	N (Clinical)	N (Contrived)	Slope	95% CI Slope	Intercept	95% CI Intercept	R
1	EDTA Venous	100	12	0.9805	0.947 - 1.014	0.5607	0.099 - 1.022	0.984
	Capillary	101	N/A	0.9628	0.928 - 1.008	0.3985	-0.167 - 0.964	0.977
2	EDTA Venous	120	11	1.0067	0.980 - 1.032	-0.1795	-0.558 - 0.199	0.989
	Heparin Venous	120	11	1.0229	1.004 - 1.042	-0.3606	-0.643 - 0.079	0.994
	Capillary	119	N/A	1.0129	0.951 - 1.075	0.0958	-0.989 - 0.798	0.943
3	EDTA Venous	119	12	0.9944	0.963 - 1.011	-0.0547	-0.295 - 0.382	0.992
	Capillary	120	N/A	0.9889	0.952 - 1.026	0.0772	-0.454 - 0.698	0.978
4	EDTA Venous	5	N/A	0.9487	0.642 - 1.255	0.7755	-3.518 - 5.069	0.985
	Capillary	23	N/A	1.0145	0.743 - 1.286	-0.3496	-4.109 - 3.410	0.861
TOTAL	EDTA Venous	349*	35	0.9858	0.969 - 1.002	0.2130	-0-029 - 0.455	0.986
	Capillary	363	N/A	0.9903	0.963 - 1.018	0.1164	-0.276 - .509	0.963

* See introductory study description.

Passing-Bablok Regression All Sites

		Passing-Bablok Regression	R
All results	Capillary	y = -0.1198 + 1.011x	0.965
	EDTA Venous	Y = 0.4867 + 0.9637x	0.986

Matrix Comparison

120 paired natural EDTA and heparin samples, ranging from 10.4 – 19.9 g/dL (EDTA) or 10.4 – 20.0 g/dL (heparin) Hgb, agreed closely and can be used interchangeably in the DiaSpect Tm system. Agreement between capillary and EDTA samples in the DiaSpect was favourable to that of the predicate system, and thus the DiaSpect Tm and predicate are substantially equivalent.

Comparison	Slope	Intercept	R
DiaSpect EDTA vs Heparin	0.9981	0.0644	0.9812
DiaSpect, Venous vs Capillary	0.9702	0.4634	0.8839
HemoPoint (predicate), Venous vs Capillary	0.8964	1.4695	0.8926

Expected Values/reference Range

Reference interval calculations were performed to verify that the results obtained for a normal reference population using the DiaSpect Tm Hemoglobin Measuring System are equivalent to published ranges (Dacie and Lewis, *Practical Haematology, Twelfth Edition*, Elsevier Limited 2017). Prospective fingerstick and venous EDTA DiaSpect Tm values from normal, healthy individuals enrolled in the method comparison studies were pooled and used. The interval between the 2.5^{th} and 97.5^{th} percentiles was taken as the reference interval. Results for subjects with no medications, capillary and EDTA venous samples combined.

Population	Age Range	Cited Reference Range
Adult Male	≥ 22 years	13.0 – 17.0 g/dL
Adult Female	≥ 22 years	12.0 – 15.0 g/dL
Child/Adolescent	> 2 years to 21 years	11.0 – 15.5 g/dL
Infant	1 month to 2 years	9.4 – 16.5 g/dL

VII. Conclusion

The DiaSpect Tm system data presented and provided is complete and supports the basis for substantial equivalence to the predicate device.