Section 5 - 510(k) Summary

510k Number
BK200520

A. 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
EKF-diagnostic GmbH
Ebendorfer Chaussee 3
Barleben, Germany 39179

Primary Contact: Karen Golomb
Phone: +1 (830) 249-0772
Fax: +1 (830) 249-0851
Email: karengolomb@ekfdiagnostics.com

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II. Device Name

Proprietary names:	DiaSpect Tm DiaSpect Tm Cuvettes
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 HemoCue Hb 301 System (BK060048, K061047).

IV. Device Description
The DiaSpect Tm system consists of an analyzer and cuvettes. The DiaSpect Tm analyzer is a spectrophotometric instrument for the measurement of 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 K2-EDTA or lithium heparin tubes in point-of-care settings and in non-anticoagulated capillary whole blood and venous whole blood drawn in K2-EDTA tubes in blood bank settings. The DiaSpect Tm system consists of the DiaSpect Tm analyzer and specifically designed disposable cuvettes. The DiaSpect Tm analyzer is only to be used with DiaSpect Tm Cuvettes. Rx only.

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VI. Comparison with Predicate

Predicate device name(s): HemoCue Hb 301 System

Predicate 510(k) number(s): BK060048, K061047

Similarities compared to the predicate device (BK060048,K061047)

Performance	Predicate Device HemoCue Hb 301 System (*BK060048, K061047*)	Candidate Device DiaSpect Tm system (*K172173*)
Indications for use	Determine hemoglobin content of whole blood	Same
Analyte	Hemoglobin	Same
Sample preparation	None	Same
Automation	Fully automated assay	Same
Calibration procedure	Factory calibrated	Same
Test methodology	Optical absorbance	Same
Sample volume	10 µL	Same
Cuvette reagent components	None	Same
Result memory	No	Same
Quality Control	Quality control materials are available	Same

Differences compared to the predicate device (BK060048, K061047)

Performance	Predicate Device HemoCue Hb 301 System (*BK060048, K061047*)	Candidate Device DiaSpect Tm system (*K172173*)
Intended Use	The HemoCue Hb 301 System is designed for quantitative point-of-care whole blood hemoglobin determination in primary care or blood donation settings using a specially designed analyzer, the HemoCue Hb 301 Analyzer, and specially designed microcuvettes, the HemoCue Hb 301 Microcuvettes. The HemoCue Hb 301 System is for In Vitro Diagnostic use only. The HemoCue Hb 301 Analyzer is only to be used with HemoCue Hb 301 Microcuvettes.	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 K2-EDTA or lithium heparin tubes in point-of-care settings and in non-anticoagulated capillary whole blood and venous whole blood drawn in K2-EDTA tubes in blood bank settings. The DiaSpect Tm system consists of the DiaSpect Tm analyzer and specifically designed disposable cuvettes. The DiaSpect Tm analyzer is only to be used with DiaSpect Tm Cuvettes. Rx only.
Sample type	Capillary, arterial or venous whole blood	Capillary or venous whole blood
Built-In Quality Control	Auto self-check at start and at regular time intervals	Auto self-check confirms each measurement
Expected values Adult Males Adult Females Children Infants	 13.0 – 18.0 g/dL 11.0 – 16.0 g/dL 2 yrs to teenage: 11.0 – 16.0 g/dL Post-natal: 10.0 – 14.0 g/dL	 13.0 – 17.0 g/dL 12.0 – 15.0 g/dL >2 yrs to 21: 11.0 – 15.5 g/dL 1 mo. to 2 yrs: 9.4 – 16.5 g/dL
Operating temperature	10 to 40°C (50 to 104°F)	10 to 42°C (50 to 107°F)
Cuvette storage	10 – 40°C (50 to 104 °C)	0 – 50°C (32 to 122 °F)
Cuvette composition	Composed of polystyrene	Composed of poly methyl methacrylate (PMMA)

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Performance	Predicate Device HemoCue Hb 301 System (*BK060048*, *K061047*)	Candidate Device DiaSpect Tm system (*K172173)*
Control Kit components	Two concentration levels of liquid controls	Three concentration levels of liquid controls
Measurement Range	0.0 – 25.6 g/dL	1.2 – 25.5 g/dL
Connectivity	Serial port	• Wireless Bluetooth Low Energy • USB
Measuring Time	3 seconds	1 second
User Interface	• Display • Beeper • One button	• Display • Beeper • Cuvette holder
Microcuvette Insertion Technique	Place on a tray	Slot in
Power Sources	• AC adapter • 4 x AA batteries	• 3.6 V integrated lithium ion rechargeable batteries • USB Adaptor
Dimensions	6.3x5.5x2.8 inch	6x3.5x1.6 inch

VII. Performance Characteristics

1. Analytical Performance

Analytical studies to determine the substantial equivalence of the DiaSpect Tm system in point-of-care settings have been previously cleared under K172173. Precision study summaries from K172173 are included as follows:

a. Precision/Reproducibility:

20-Day Precision

Reproducibility was conducted at three intended use sites over 20 operating days using three DiaSpect Cuvette lots (one lot per site), three DiaSpect Tm Analyzers (one instrument per site), and one lot of DiaSpect Controls at three levels (low, medium and high). Each control set was run in duplicate twice daily for 20 days, by two operators at each site. A total of 160 test results were generated for each control level at each site. SD and %CV for within-run, between-run, between-day, between-operator, and between-site were calculated for each site and all sites combined. Reproducibility results at all test sites were within the defined acceptance criteria.

Table 1 20-Day precision data met the criteria of <7% CV.

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
Low	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%
Medium	240	12.58	0.11, 0.8%	0.05, 0.38%	0.03, 0.22%	0, 0%	0.05, 0.47%	0.14, 1.09%
High	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%

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Single-Day Precision
Single-day precision was performed at a single site using K2-EDTA venous whole blood. Five donors provided five samples (one sample each), some of which were manipulated to increase or decrease hemoglobin levels. The study was performed at a single site using three instruments, three lots of cuvettes, and three operators. Each of three operators ran duplicate tests on all five levels, providing 54 measurements for each level. Single-day precision results were within the defined acceptance criteria.

Table 2 Single-Day precision data met the criteria of <7% CV.

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, .06%)	(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
Please refer to submission K172173.

c. Traceability, Stability, Expected values (Controls, Calibrators)
The DiaSpect Control HBT is produced in three concentrations that correspond to three levels of human hemoglobin.

d. Detection Limit:
Please refer to submission K172173.

e. Analytical specificity:
Please refer to submission K172173.

f. Assay cut-off:
Not applicable

g. Stability
Please refer to submission K172173.

h. Calibration
The DiaSpect Tm analyzer is factory calibrated and requires no further calibration.

i. Quality Control
DiaSpect control solutions are available to facilitate compliance with local, state and/or federal regulations or accreditation requirements. The DiaSpect Control HBT is produced in three concentrations that correspond to three known 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.

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2. Method Comparison Studies

Method comparison studies were conducted with finger stick capillary whole blood and paired K2-EDTA venous whole blood at blood bank settings. A total of 150 capillary and 147 venous blood donors were tested with the DiaSpect Tm and HemoCue Hb 301 at two sites.

DiaSpect Tm vs HemoCue Hb 301 (linear regression)

Site	Matrix	N	Slope (95% CI)	Intercept (95% CI)	r
1	Capillary	75	0.9644 (0.8911 ~ 1.0377)	0.1086 (-1.011 ~ 1.228)	0.951
	Venous	72	1.1521 (1.0967 ~ 1.2074)	-2.8551 (-3.7028 ~ -2.0074)	0.980
2	Capillary	75	0.9472 (0.8988 ~ 0.9957)	0.3588 (-0.3555 ~ 1.0731)	0.977
	Venous	75	1.1784 (1.1341 ~ 1.2227)	-2.7653 (-3.4184 ~ -2.1121)	0.987
Total	Capillary	150	0.9541 (0.9134 ~ 0.9948)	0.2619 (-0.3496 ~ 0.8733)	0.967
	Venous	147	1.1465 (1.1068 ~ 1.1863)	-2.5299 (-3.4183 ~ -2.1122)	0.978

DiaSpect Tm vs HemoCue Hb 301 (Passing-Bablok regression)

Site #	Matrix	N	Slope (95% CI)	Intercept (95% CI)	r
ALL	Capillary	150	1.000 (0.9512 ~ 1.032)	-0.45 (-1.011 ~ 0.2805)	0.967
ALL	Venous	147	1.140 (1.100 ~ 1.179)	-2.477 (-3.067 ~ -1.895	0.978

The bias of the DiaSpect Tm at hemoglobin acceptance levels for donors was calculated from the regression curves using the Hb 301 as the reference method.

Donor Cutoff vs Hb 301	DiaSpect Tm Capillary		DiaSpect Tm Venous	
	Hb Level	% Bias	Hb Level	% Bias
Adult Female, 12.5 g/dL	12.2 g/dL	-2.4%	11.8	-5.6%
Adult Male, 13 g/dL	12.7 g/dL	-2.3%	12.4	-4.8%

Using the Hb 301 as the reference method, the agreements for blood donor acceptance at these cutoff levels are as follows:

Capillary All Donors	Hb 301 ≥Cutoff	Hb 301 <Cutoff
DiaSpect Tm ≥Cutoff	127	2
DiaSpect Tm <Cutoff	7	14

Agreement (Score 95% CI)
Accept = 127/134 = 94.8% (89.6~97.4%)
Reject = 14/16 = 87.5% (64.0~96.5%)

Venous All Donors	Hb 301 ≥Cutoff	Hb 301 <Cutoff
DiaSpect Tm ≥Cutoff	120	1
DiaSpect Tm <Cutoff	13	13

Agreement (Score 95% CI)
Accept = 120/133 = 90.2% (84.0~94.2%)
Reject = 13/14 = 92.9% (68.5~98.7%)

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The negative bias observed for the DiaSpect Tm was resolved by comparing both test methods to a laboratory reference method. In a separate study conducted at one site, 100 capillary and 100 venous samples were tested with the DiaSpect Tm and HemoCue Hb 301 and compared with the same venous samples that were also tested with the Sysmex XP-300. The DiaSpect Tm was found to be substantially equivalent to the Sysmex XP-300 (calibrated to the hemiglobincyanide method, HiCN), while the HemoCue Hb 301 consistently provided results that are higher by approximately 0.6 g/dL. The results are summarized below.

The bias of the DiaSpect Tm at hemoglobin acceptance levels for donors was calculated from the regression curves using the Sysmex XP-300 as the reference method.

Donor Cutoff vs XP-300	**DiaSpect Tm Capillary**		**DiaSpect Tm Venous**	
	Hb Level	**% Bias**	**Hb Level**	**% Bias**
Adult Female, 12.5 g/dL	12.56	0.5%	12.53	0.2%
Adult Male, 13 g/dL	13.05	0.4%	13.07	0.7%

The bias of the Hb 301 at hemoglobin acceptance levels for donors was calculated from the regression curves using the Sysmex XP-300 as the reference method.

Donor Cutoff vs XP-300	**Hb 301 Capillary**		**Hb 301 Venous**	
	Hb Level	**% Bias**	**Hb Level**	**% Bias**
Adult Female, 12.5 g/dL	13.12	5.0%	13.03	4.2%
Adult Male, 13 g/dL	13.62	4.8%	13.55	4.2%

Using the Sysmex-XP-300 as the reference method, the agreements for blood donor acceptance at these cutoff levels are as follows:

Capillary All Donors	Sysmex XP-300 ≥Cutoff	Sysmex XP-300 <Cutoff
DiaSpect Tm ≥Cutoff	75	3
DiaSpect Tm <Cutoff	6	16

Agreement (Score 95% CI)
Accept = 75/81 = 92.6% (84.8~96.6%)
Reject = 16/19 = 84.2% (62.4~94.5%)

Venous All Donors	Sysmex XP-300 ≥Cutoff	Sysmex XP-300 <Cutoff
DiaSpect Tm ≥Cutoff	77	0
DiaSpect Tm <Cutoff	4	19

Agreement (Score 95% CI)
Accept = 77/81 = 95.1% (88.0~98.1%)
Reject = 19/19 = 100.0% (83.2~100.0%)

Matrix Comparison
Please refer to submission K172173.

VII. Conclusion
The DiaSpect Tm data presented and provided is complete and supports the basis for substantial equivalence to the predicate device for use in blood bank settings.