April 19, 2022

Helena Laboratories, Corp.
Justin Padia
Director of Regulatory Affairs
1530 Lingbergh Drive
Beaumont, Texas 77707

Re: K192931
Trade/Device Name: V8 Nexus Hemoglobin Ultrascreen, V8 AFSA2 Hemo Control
Regulation Number: 21 CFR 864.7415
Regulation Name: Abnormal Hemoglobin Assay
Regulatory Class: Class II
Product Code: GKA, JBD
Dated: October 16, 2019
Received: October 17, 2019

Dear Justin Padia:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Min Wu, Ph.D.
Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K192931

Device Name
V8 Nexus Hemoglobin UltraScreen (Catalog #1828 / Catalog #801100)

V8 Nexus AFSA2 Hemo Control (Catalog #1812)

Indications for Use *(Describe)*

The V8 Nexus Hemoglobin UltraScreen method is designed for the separation of normal hemoglobins (A, A2, and F) in human blood samples, and for the detection of major hemoglobins variants (S and C) by using a capillary zone electrophoresis (CZE) buffer with the V8 instrument. The V8 Nexus Hemoglobin UltraScreen test is indicated for use in patients 2 years of age and older. This test is designed for in-vitro diagnostic use only in conjunction with other laboratory and clinical findings.

The V8 instrument is an automated analyzer which performs a complete hemoglobin profile for quantitative analysis of the normal hemoglobin fractions A, A2 and F and for the detection of major hemoglobin variants S and C. The assay is performed on the hemolysate of venous whole blood collected in tubes containing K2EDTA as the anticoagulant.

The V8 AFSA2 Hemo Control (Cat. No. 1812) is to be used as a quantitative and/or qualitative control for the Hemoglobin UltraScreen on the V8 Capillary Electrophoresis (CE) system.

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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510(k) Summary

This section includes a **description** of the device: including the indications for use and technology; a comparison to the predicate device; and a concise summary for any performance testing in the submission.

Purpose for Submission:

New Device

Type of Test:

Quantitative, Capillary Zone Electrophoresis

Submitter's Name:

Helena Laboratories, Corp.

Address: 1530 Lindbergh Drive
Beaumont, TX 77707

Phone: (409) 842-3714

Date Summary Prepared: 4/13/2022

Proprietary Names:

V8 Nexus Hemoglobin UltraScreen (Catalog #1828 / Cat. #801100)
V8 $AFSA_2$ Hemo Control (Catalog #1812)

Device Classification:

Product: V8 Nexus Hemoglobin UltraScreen
Classification: Class II
Panel: Hematology
Product Code: GKA
C. F. R. Section: 864.7415

Product: V8 $AFSA_2$ Hemo Control
Classification: Class II
Panel: Hematology
Product Code: JBD
C. F. R. Section: 864.7440

Intended Use:

The V8 Nexus Hemoglobin UltraScreen method is designed for the separation of normal hemoglobins (A, A2, and F) in human blood samples, and for the detection of major hemoglobins variants (S and C) by using a capillary zone electrophoresis (CZE) buffer with the V8 instrument. The V8 Nexus Hemoglobin UltraScreen test is indicated for use in patients 2 years of age and older. This test is designed for in-vitro diagnostic use only in conjunction with other laboratory and clinical findings.

The V8 instrument is an automated analyzer which performs a complete hemoglobin profile for quantitative analysis of the normal hemoglobin fractions A, A2 and F and for the detection of major hemoglobin variants S and C. The assay is performed on the hemolysate of venous whole blood collected in tubes containing K2EDTA as the anticoagulant.

The V8 AFSA2 Hemo Control (Cat. No. 1812) is to be used as a quantitative and/or qualitative control for the Hemoglobin UltraScreen on the V8 Capillary Electrophoresis (CE) system.

Predicate Comparison for Submission:

Comparison with Predicate Device:

These devices have the same intended use and indications for use and similar technological characteristics and principles of operation. Sample hemolysis is performed automatically by an instrument on EDTA anti-coagulant whole blood specimens.

They are run on different instrumentation platforms; however, both are based on similar technological principles.

The table below provides a description of Helena's device, conveying similarities and differences between the assay and the predicate device:

V8 Nexus Hemoglobin UltraScreen Substantial Equivalence – Comparison to Predicate Device

	Device	**Predicate**
	Helena Laboratories V8 Nexus Hemoglobin UltraScreen Test	**Sebia CAPILLARYS Hemoglobin(E) Test**
510(k) Number	K192931	K112491
Type of Test	Quantitative, Capillary Zone Electrophoresis	Quantitative, Capillary Electrophoresis
Measurand	Hemoglobin A, F, A_2, S, C	Hemoglobin A, F, A_2, S, C, E, D
Intended User	Clinical Laboratory Professional	Clinical Laboratory Professional
Intended Use	*In vitro* diagnostic hemoglobin test for the quantitative detection of individual hemoglobin fractions A, A_2 and F and qualitative detection of major hemoglobin variants S and C from EDTA anti-coagulated human whole blood specimens.	*In vitro* diagnostic hemoglobin test for the quantitative detection of individual hemoglobin fractions A, A_2 and F and qualitative detection of major hemoglobin variants S, C, E and D from EDTA anti-coagulated human whole blood specimens.

Specimen Type	Hemolysate of venous whole blood	Hemolysate of whole blood
Anticoagulant	K_2EDTA	K_2EDTA and K_3EDTA
Sample Preparation	Sample hemolysis performed automatically by an instrument	Sample hemolysis performed automatically by an instrument
Technological Detection Principles	Free solution capillary electrophoresis – protein separation occurs, in an electrolyte medium, according to their electrophoretic mobilities. Electropherograms show separated fractions based on mass to charge ratio.	Free solution capillary electrophoresis (FSCE): protein separation in an alkaline buffer (pH 9.4) according to their charge to the electrolyte pH and electroosmotic flow. Electropherograms show separated fractions according to their charge.
Control for Migration / Other	V8 $AFSA_2$ Hemo Control	Normal Hb A2 control; HB AFSC
Absorbance Wavelength	415 nm	415 nm
Instrument	V8 Instrument	CAPILLARYS 2 Instrument

Sample Hemolysis

V8 Nexus Hemoglobin UltraScreen – Performed automatically by the system

Sebia CAPILLARYS Hemoglobin(E) - same

Collection Tubes

V8 Nexus Hemoglobin UltraScreen – EDTA anticoagulant

Sebia CAPILLARYS Hemoglobin(E) - same

Separation System

V8 Nexus Hemoglobin UltraScreen – Free solution capillary electrophoresis – protein separation occurs, in an electrolyte medium, according to their electrophoretic mobilities. Electropherograms show separated fractions based on mass to charge ratio.

Sebia CAPILLARYS Hemoglobin(E) – Free solution capillary electrophoresis (FSCE): protein separation in an alkaline buffer (pH 9.4) according to their charge to the electrolyte pH and electroosmotic flow. Electrophoretograms show separated fractions according to their charge.

Number of Separation Units

V8 Nexus Hemoglobin UltraScreen – 8 parallel capillaries

Sebia CAPILLARYS Hemoglobin(E) - 7 parallel capillaries

Automated Sample Introduction

V8 Nexus Hemoglobin UltraScreen – Continuous loading with sample racks

Sebia CAPILLARYS Hemoglobin(E) - Continuous loading with sample racks

Sample Processing

V8 Nexus Hemoglobin UltraScreen – Aspiration of whole blood from open tube

Sebia CAPILLARYS Hemoglobin(E) – Aspiration of hemolysate of packed red blood cells from uncapped tube

Assay Throughput

V8 Nexus Hemoglobin UltraScreen – 32 samples / hour

Sebia CAPILLARYS Hemoglobin(E) – 33 samples/ hour

Kit Components

V8 Nexus Hemoglobin UltraScreen – All components supplied together

Sebia CAPILLARYS Hemoglobin(E) - All components supplied together

Sample Identification

V8 Nexus Hemoglobin UltraScreen – Barcode reader racks and tubes

Sebia CAPILLARYS Hemoglobin(E) - Barcode reader racks and tubes

Absorbance Wavelength

V8 Nexus Hemoglobin UltraScreen – 415 nm

Sebia CAPILLARYS Hemoglobin(E) - 415 nm

Controls for Test:

The **V8 AFSA2 Hemo Control** (Cat. No. 1812) is to be used as a quantitative and/or qualitative control for the Hemoglobin UltraScreen on the V8 Capillary Electrophoresis (CE) system.

Predicate Controls:

Sebia Normal Hb A2 Control/ Migration control

Sebia Hb AFSC Control

Comparison Table

Item	Device	Predicate
Product	V8 $AFSA_2$ Hemo Control	Normal Hb A2 Control / Migration Control & HB AFSC Control
Intended use	Control material derived from whole blood with a quantitative range to ensure system performance	Same
Matrix	Human serum based	Same
Form	Liquid	Lyophilized
Visualized fractions	Four fractions (Hb A, F, S, A_2)	Same
Storage	2-8°C	Same

Summary of Performance Testing – Bench:

Performance Testing – Precision/Reproducibility Studies

The precision/reproducibility of the V8 Nexus UltraScreen procedure was evaluated following CLSI EP05-A3 guidelines. The means, standard deviations and coefficients of variation were calculated for each hemoglobin fraction.

20-day Precision/Reproducibility Study using one instrument, one kit lot with AFSA2 and AFSC hemoglobin controls

AFSA2 and AFSC hemoglobin controls were run using a single V8 Nexus instrument and a single UltraScreen kit for 20 days, twice per day with 8 reps per run. Within capillary, Between capillary, Between run, Between day and Total reproducibility estimates were calculated (mean fraction %, SD and CV).

Fraction	*N*	*Mean %*	*Within Capillary SD, CV*	*Between Capillary SD, CV*	*Between Run SD, CV*	*Between Day SD, CV*	*Total SD, CV*
Hb A	320	43.2	0.13, 0.3	1.64, 5.0	0.39, 1.2	0.39, 1.2	1.77, 5.3
Hb F	320	33.1	0.10, 0.3	1.09, 3.3	0.26, 0.8	0.26, 0.8	1.13, 3.4
Hb S	320	21.7	0.15, 0.7	0.09, 0.4	0.22, 1.0	0.22, 1.0	0.37, 1.7
Hb A2	320	1.9	0.07, 3.7	0.03, 1.6	0.07, 3.7	0.07, 3.7	0.11, 5.8

Fraction	*N*	*Mean %*	*Within Capillary SD, CV*	*Between Capillary SD, CV*	*Between Run SD, CV*	*Between Day SD, CV*	*Total SD, CV*
Hb A	320	29.3	0.09, 0.3	0.38, 1.3	0.18, 0.6	0.18, 0.6	0.47, 1.6
Hb F	320	24.1	0.07, 0.3	0.51, 2.1	0.17, 0.7	0.19, 0.8	0.60, 2.5
Hb S	320	25.0	0.10, 0.4	0.13, 0.5	0.15, 0.6	0.18, 0.7	0.33, 1.3
Hb C	320	21.6	0.11, 0.5	0.04, 0.2	0.15, 0.7	0.15, 0.7	0.22, 1.0

5-day reproducibility study with three instruments and one kit

Precision/reproducibility studies were performed using fresh and refrigerated venous K2-EDTA patient samples with known hemoglobin variants. Normal Hb AA2, Hb AF (elevated F), Hb ASA2 (elevated S and A2) and Hb AA2C (elevated C and A2) were analyzed over the course of the 5 day x 2 runs/day x 8 reps per run study. One UltraScreen lot, three V8 Nexus instruments and a single operator were employed. Within run, Between run, Between day, Between instrument and Total reproducibility estimates were calculated (mean fraction %, SD and CV).

HbA Sample	*N*	*Mean %*	*Within run SD, CV*	*Between run SD, CV*	*Between day SD, CV*	*Between instrument SD, CV*	*Total SD, CV*
1	240	96.9	0.0, 0.0	0.0, 0.0	0.10, 0.1	0.10, 0.1	0.10, 0.1
2	240	34.8	0.35, 1.0	0.66, 1.9	0.42, 1.2	0.42, 1.2	0.87, 2.5
3	240	61.0	0.37, 0.6	0.12, 0.2	0.43, 0.7	0.67, 1.1	0.79, 1.3
4	240	58.0	0.35, 0.6	0.29, 0.5	0.58, 1.0	0.70, 1.2	0.93, 1.6
Hb F Sample	*N*	*Mean %*	*Within run SD, CV*	*Between run SD, CV*	*Between day SD, CV*	*Between instrument SD, CV*	*Total SD, CV*
2	240	65.2	0.33, 0.5	0.65, 1.0	0.46, 0.7	0.39, 0.6	0.85, 1.3
Hb A2 Sample	*N*	*Mean %*	*Within run SD, CV*	*Between run SD, CV*	*Between day SD, CV*	*Between instrument SD, CV*	*Total SD, CV*
1	240	3.1	0.05, 1.5	0.00, 0.1	0.05, 1.6	0.05, 1.6	0.07, 2.2
3	240	3.6	0.05, 1.3	0.01, 0.4	0.05, 1.3	0.05, 1.3	0.07, 1.9
4	240	5.5	0.07, 1.2	0.06, 1.1	0.07, 1.2	0.07, 1.2	0.12, 2.1
Hb S Sample	*N*	*Mean %*	*Within run SD, CV*	*Between run SD, CV*	*Between day SD, CV*	*Between instrument SD, CV*	*Total SD, CV*
3	240	34.5	0.35, 1.0	0.17, 0.5	0.38, 1.1	0.59, 1.7	0.76, 2.2
Hb C Sample	*N*	*Mean %*	*Within run SD, CV*	*Between run SD, CV*	*Between day SD, CV*	*Between instrument SD, CV*	*Total SD, CV*
4	240	36.5	0.37, 1.0	0.29, 0.8	0.58, 1.6	0.73, 2.0	0.95, 2.6

Three site precision/reproducibility study using three instruments and one kit lot

Site to site precision of the UltraScreen Hemoglobin assay was assessed at three different sites. Nine samples of varying levels of hemoglobin A, A2, F, S and C were prepared by controlled proportion mixing to generate hemoglobin percentages for each fraction in the normal and pathologic range, where applicable. One V8 instrument, one lot of V8 Hemoglobin UltraScreen reagent kit (same at all 3 sites (1 internal and 2 external)) and a single operator per site were utilized. The tests were run at 3 Sites x 5 days x 2 runs/day x 4 reps/run. Within run, Between run, Between day, Between site and Total reproducibility estimates were calculated (mean fraction %, SD and CV).

Hb A Sample	*N*	*Mean %*	*Within run SD, CV*	*Between run SD, CV*	*Between day SD, CV*	*Between Site SD, CV*	*Total SD, CV*
1	120	97.2	0.00, 0.0	0.00, 0.0	0.10, 0.1	0.10, 0.1	0.10, 0.1
2	120	74.7	0.30, 0.4	0.52, 0.7	0.37, 0.5	0.45, 0.6	0.82, 1.1
3	120	87.4	0.26, 0.3	0.26, 0.3	0.26, 0.3	0.44, 0.5	0.61, 0.7
4	120	59.3	0.18, 0.3	0.24, 0.4	0.18, 0.3	0.18, 0.3	0.36, 0.6
5	120	76.6	0.23, 0.3	0.00, 0.0	0.23, 0.3	0.38, 0.5	0.54, 0.7
6	120	84.9	0.25, 0.3	0.00, 0.0	0.34, 0.4	0.51, 0.6	0.76, 0.9
7	120	57.1	0.34, 0.6	0.06, 0.1	0.34, 0.6	0.34, 0.6	0.51, 0.9
8	120	78.9	0.24, 0.3	0.32, 0.4	0.32, 0.4	0.32, 0.4	0.51, 0.6
9	120	87.9	0.18, 0.2	0.26, 0.3	0.18, 0.2	0.26, 0.3	0.44, 0.5

Hb F Sample	*N*	*Mean %*	*Within run SD, CV*	*Between run SD, CV*	*Between day SD, CV*	*Between Site SD, CV*	*Total SD, CV*
2	120	23.3	0.33, 1.4	0.58, 2.5	0.35, 1.5	0.42, 1.8	0.82, 3.5
3	120	10.1	0.23, 2.3	0.25, 2.5	0.27, 2.7	0.39, 3.9	0.62, 6.1
Hb A2 Sample	*N*	*Mean %*	*Within run SD, CV*	*Between run SD, CV*	*Between day SD, CV*	*Between Site SD, CV*	*Total SD, CV*
1	120	2.8	0.03, 1.1	0.02, 0.7	0.03, 1.1	0.03, 1.1	0.05, 1.8
2	120	2.0	0.03, 1.5	0.01, 0.5	0.03, 1.5	0.03, 1.5	0.05, 2.5
3	120	2.5	0.05, 2.0	0.06, 2.4	0.05, 2.0	0.05, 2.0	0.09, 3.6
4	120	3.5	0.03, 0.9	0.0, 0.0	0.03, 0.9	0.03, 0.9	0.04, 1.1
5	120	3.0	0.04, 1.3	0.01, 0.4	0.04, 1.3	0.04, 1.3	0.06, 2.0
6	120	3.2	0.05, 1.6	0.04, 1.3	0.05, 1.6	0.05, 1.6	0.08, 2.5
7	120	5.6	0.06, 1.1	0.07, 1.3	0.06, 1.1	0.06, 1.1	0.11, 2.0
8	120	4.0	0.04, 1.0	0.01, 0.3	0.04, 1.0	0.04, 1.0	0.06, 1.5
9	120	3.5	0.05, 1.4	0.02, 0.6	0.05, 1.4	0.05, 1.4	0.07, 2.0
Hb S Sample	*N*	*Mean %*	*Within run SD, CV*	*Between run SD, CV*	*Between day SD, CV*	*Between Site SD, CV*	*Total SD, CV*
4	120	37.2	0.19, 0.5	0.26, 0.7	0.19, 0.5	0.19, 0.5	0.37, 1.0

5	120	20.2	0.20, 1.0	0.04, 0.2	0.24, 1.2	0.36, 1.8	0.51, 2.5
6	120	12.1	0.21, 1.7	0.05, 0.4	0.31, 2.6	0.56, 4.6	0.74, 6.1
Hb C Sample	*N*	*Mean %*	*Within run SD, CV*	*Between run SD, CV*	*Between day SD, CV*	*Between Site SD, CV*	*Total SD, CV*
7	120	37.3	0.34, 0.9	0.07, 0.2	0.34, 0.9	0.37, 1.0	0.52, 1.4
8	120	17.1	0.24, 1.4	0.29, 1.7	0.31, 1.8	0.32, 1.9	0.53, 3.1
9	120	8.6	0.15, 1.7	0.33, 3.8	0.21, 2.4	0.24, 2.8	0.46, 5.3

Reagent Kit Lot Precision/Reproducibility Using AFSA2

Reagent lot precision/reproducibility studies were performed using one lot of AFSA2 control, three lots of V8 Hemoglobin UltraScreen reagent kits, one V8 Nexus instrument and one operator. The tests were run 5 days x 2 runs/day x 8 reps/run. Within run, Between run, Between day, Between lot and Total reproducibility estimates were calculated (mean fraction %, SD and CV).

Sample	*N*	*Mean %*	*Within run SD, CV*	*Between run SD, CV*	*Between day SD, CV*	*Between Lot SD, CV*	*Total SD, CV*
A	240	42.9	0.26, 0.6	1.63, 3.8	0.26, 0.6	0.43, 1.0	1.72, 4.0
F	240	33.3	0.17, 0.5	1.03, 3.1	0.20, 0.6	0.27, 0.8	1.10, 3.3
S	240	21.8	0.26, 1.2	0.57, 2.6	0.37, 1.4	0.57, 2.6	0.92, 4.2
A2	240	2.0	0.07, 3.5	0.07, 3.4	0.09, 4.4	0.09, 4.5	0.14, 7.0

Performance Testing Summary - Linearity

The linearity of the V8 Nexus UltraScreen procedure was evaluated following CLSI EP06-A guidelines. Linearity studies were performed using the a single V8 Nexus Hemoglobin UltraScreen reagent kit, a single V8 Nexus and the indicated venous K2-EDTA samples containing different levels of each hemoglobin fraction (9 levels for each fraction). The tests were determined to be linear over the following ranges: HbA: 3.7-97.2%, HbF: 1.1-68.7%, HbS: 5.8-78.8%, HbA2: 1.7-7.6%, HbC: 1.4-42.6%.

Performance Testing Summary – Limit of Detection (LOD), Limit of Quantitation (LOQ):

Limit of Detection (LOD) and Limits of Quantitation (LOQ) were assigned based on the determined lower limits of linearity for each hemoglobin fraction.

Fraction	LOD/LOQ %
Hb A	3.7
Hb A2	1.7
Hb F	1.1
Hb S	5.8
Hb C	1.4

Performance Testing Summary – Analytical Specificity:

Interference studies were conducted on venous K2-EDTA whole blood samples: 5 Hb A levels, 4 Hb A2 levels (2 normal and 2 elevated), 2 levels of Hb F, 1 level of Hb S and Hb C. Lipids (Sigma Intralipid #I141), Unconjugated Bilirubin (CalBiochem #2011-1GM) and Conjugated Bilirubin (CalBioChem #201102) and were analyzed with respect to interfering with hemoglobin quantitation. Lipids were tested at 0-25 g/L. Unconjugated and Conjugated bilirubin were tested at 0-25 mg/dL. Each hemoglobin fraction level listed above were analyzed four times per interferent level. No interference was observed.

Interferent	Maximum concentration
Lipids	25 g/L
Unconjugated Bilirubin	25 mg/dL
Conjugated Bilirubin	25 mg/dL

Interference: K2-EDTA

Interference studies were conducted on fresh venous K2-EDTA whole blood samples: 3 Hb A levels, 3 Hb A2 levels (1 normal and 2 elevated), 1 level of Hb S and Hb C, respectively.. K2-EDTA concentrations were analyzed with respect to interfering with hemoglobin quantitation. K2-EDTA was tested at 3.6 mg/mL (normal) and 7.2 mg/mL (elevated). No interference was observed.

Interferent	Maximum concentration
K2-EDTA	7.2 mg/mL

Summary of Performance Testing – Comparison Studies:

Clinical testing was done at three external sites using the V8 Nexus Hemoglobin UltraScreen test to verify the performance characteristics of the system. Testing was done in accordance with the instructions specified in the V8 Operator Manual and the package insert for the assay.

Three external sites compared V8 Nexus Hemoglobin UltraScreen to Sebia's Capillarys Hemoglobin(E) Test (K112491). Each site received a different lot of the V8 Nexus Hemoglobin UltraScreen reagent kits (3 in total).

Fresh venous K2-EDTA-anticoagulated whole blood was used for the analysis. From a total of 439 patient samples—320 hemoglobin A, 412 hemoglobin A2, and 175 hemoglobin F quantitation's were performed. 143 presumptive hemoglobin S and 33 presumptive hemoglobin C. A single data point was collected per platform utilized. UltraScreen data points were accepted only if the data points were within the UltraScreen linearity range established for each hemoglobin fraction. Passing-Bablok regression was utilized to generate regression statistics.

Site 1:
The patient population for Site 1 was 40 normal samples and 141 pathologic samples were analyzed. The following individual determinations were performed: 122 hemoglobin A, 179 hemoglobin A2, 71 hemoglobin F, 70 hemoglobin S and 30 hemoglobin C. Two Hb F differences were >20%. However, these were associated with phenotypes where F is not the diagnosing variant.

Fraction	N	Range	R	Slope	95% CI	Intercept	95% CI
Hb A	122	8.7-97.2	0.999	1.007	1.000,1.017	-0.74	-1.67,0.20
Hb A2	179	1.6-6.1	0.995	1.000	1.000,1.000	0.00	0.00,0.00
Hb F	71	1.1-44.3	0.999	1.000	0.996,1.003	0.10	0.06,0.11
Hb S	70	19.7-76.8	0.998	0.953	0.941,0.965	2.53	1.89,3.04
Hb C	30	23.6-42.3	0.975	1.00	0.923,1.114	0.85	-2.84,3.30

Site 2:
The patient population for Site 2 was 54 normal samples and 95 pathologic samples were analyzed. The following individual determinations were performed: 119 hemoglobin A, 128 hemoglobin A2, 65 hemoglobin F, and 41 hemoglobin S. Six Hb A differences were >20%. However, these were associated with phenotypes where A is not the diagnosing variant. Five Hb A2 differences were >20%. Four were associated with hemoglobin variants where A2 is not diagnostic. The other Hb A2 difference >20% was within or below normal range for both analytes. Thirty-one Hb F differences of >20% were associated with twenty-two AFA2 phenotypes with elevated F. No change in diagnosis would result. The other nine were associated with hemoglobin phenotypes where F is not the diagnostic factor.

Fraction	N	Range	R	Slope	95% CI	Intercept	95% CI
Hb A	119	6.8-97.2	0.999	0.973	0.954,0.991	2.40	0.71,4.17
Hb A2	128	1.8-5.9	0.958	1.000	1.000,1.000	0.20	0.20,0.20
Hb F	65	1.1-68.0	0.993	1.063	1.019,1.091	0.82	0.74,1.06
Hb S	41	13.1-78.6	0.995	0.921	0.897,0.952	1.09	-0.91,2.53
Hb C	ND	ND	ND	ND	ND	ND	ND

Site 3:
The patient population for Site 3 was 38 normal samples and 71 pathologic samples were analyzed. The following individual determinations were performed: 79 hemoglobin A, 105 hemoglobin A2, 39 hemoglobin F, and 32 hemoglobin S. Three Hemoglobin C determinations were performed but not analyzed by individual site. These data points were included in the compiled analysis. Twelve Hb A2 differences were >20%. Nine were associated with hemoglobin variants where A2 is not diagnostic. Two were Hb A2 difference >20% were within or below normal range for both analytes. The other Hb A2 difference was associated with an AA2 thalassemia condition where diagnosis would not be changed. Twenty-three Hb F differences of >20% were associated with thirteen AFA2 phenotypes with elevated F. No change in diagnosis would result. The other ten were associated with hemoglobin phenotypes where F is not the diagnostic factor.

Fraction	N	Range	R	Slope	95% CI	Intercept	95% CI
Hb A	79	10.5-97.2	0.998	0.973	0.949,0.989	2.55	1.28,4.74
Hb A2	105	1.9-6.9	0.931	0.963	0.893,1.000	-0.09	-2.0,0.17
Hb F	39	1.2-31.9	0.988	1.082	1.000,1.149	0.86	0.57,1.10
Hb S	32	9.6-73.9	0.995	0.908	0.864,0.939	2.37	1.04,3.91
Hb C	ND	ND	ND	ND	ND	ND	ND

Sites 1-3 Combined:

Fraction	N	Range	R	Slope	95% CI	Intercept	95% CI
Hb A	320	6.8-97.2	0.999	0.990	0.984,0.998	0.78	0.12,1.40
Hb A2	412	1.6-6.9	0.957	1.000	1.000,1.000	0.05	0.05,0.05
Hb F	175	1.1-68.0	0.993	1.000	0.985,1.020	0.70	0.52,0.73
Hb S	143	9.6-78.6	0.994	0.929	0.909,0.948	2.40	1.67,3.22
Hb C	33	23.6-42.3	0.975	1.000	0.925,1.103	0.60	-2.70,3.06

Reference Range Assignment

To establish a reference range, 132 normal hemoglobin samples in total were analyzed at 3 sites for Hemoglobin A and Hemoglobin A2 levels using the V8 Nexus Hemoglobin UltraScreen assay. The resulting 95% confidence limits reference ranges are as follows:

Hb A: 96.9-97.2%
Hb A2: 2.1-3.4%

Note: The UltraScreen assay does not report quantitation of hemoglobin F below 0.9%. The level of Hemoglobin F in a non-neonatal population is below the reportable limit of the assay.

Conclusion:

The information provided in this premarket submission is complete and has demonstrated safety and efficacy. Helena Laboratories has concluded that this submission supports a substantial equivalence decision, as compared to the predicate device.