510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K211840

B Applicant

Sight Diagnostics Ltd.

C Proprietary and Established Names

Sight OLO

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
GKZ	Class II	21 CFR 864.5220 - Automated Differential Cell Counter	HE - Hematology

II Submission/Device Overview:

A Purpose for Submission:

Modification of a cleared device

B Measurand:

WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EOS%/# and BASO%/#

C Type of Test:

Quantitative complete blood count (CBC) with 5-part leukocyte differential: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EOS%/# and BASO%/#.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Sight OLO is a quantitative multi-parameter automated hematology analyzer intended for in vitro diagnostic use in screening capillary or venous whole blood samples collected in K2EDTA blood collection tubes, or fingertip samples collected using the Sight OLO test kit micro-capillary tubes.

When used with the Sight OLO cartridge, the Sight OLO utilizes computer imaging and computer vision algorithms to enumerate the following CBC parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, NEUT%/#, LYMPH %/#, MONO %/#, EO%/#, and BASO%/#.

The Sight OLO is indicated for use by clinical laboratories to identify and classify one or more of the formed elements of blood in children 3 months and above, adolescents and adults.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

Sight OLO

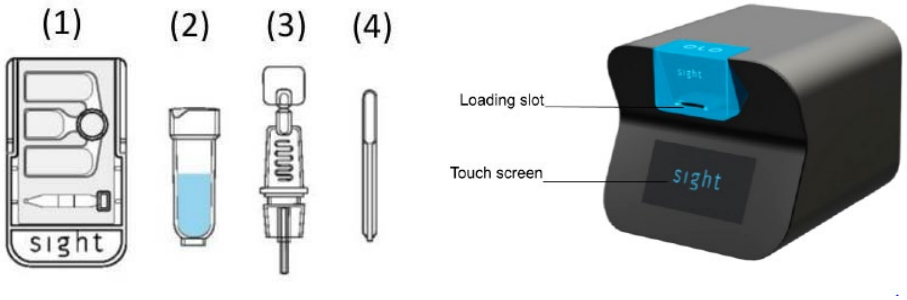
IV Device/System Characteristics:

A Device Description:

The Sight OLO device was cleared under K190898. Since its original clearance, the designs and components of the Sight OLO have remained the same, whereas the analysis software algorithms of the Sight OLO have been updated. However, the Sight OLO remains a quantitative, multiparameter, automated in vitro diagnostic hematology analyzer that screens whole blood samples collected from venous and/or capillary blood and provides results for complete blood count (CBC) parameters and a 5-part leukocyte differential.

The Sight OLO device is a compact computer vision-based platform for blood analysis. The Sight OLO device consists of a scanning and analyzing unit and a CBC test kit, which includes a disposable cartridge (1). The disposable cartridge contains an imaging chamber and a hemoglobin (Hgb) measurement cavity. In addition to the disposable cartridge, the CBC test kit also includes a mixing bottle (2) containing 1333 µL diluent and sealed with pierceable foil, a dropper cap (3) integrated with 10 µL end-to-end micro-capillary and containing dried fluorescent staining reagents, and a 17 µL micro-capillary (4, off the shelf). Pre-dilution and staining of blood sample occurs in the mixing bottle and blood sample is added to the disposable

cartridge, which is then inserted into the device through the loading slot. Using dedicated staining, the proposed platform provides CBC analysis. The device is operated through the touch screen interface.



B Principle of Operation:

The Sight OLO device is a computer vision based platform for blood analysis. The platform combines computer-vision algorithms for image processing to identify and quantify blood components (e.g., red blood cells) and their characteristics (e.g., cell volume) in an automated fashion.

The disposable cartridge loaded with whole blood sample is inserted into the device for automatic staining and monolayer formation. The device uses computer-vision algorithms to visually scan a stained blood sample under a florescence microscope. The device utilizes three wavelengths bright-field images, and fluorescence mages to derive the complete blood count of the sample. The captured images are analyzed, and the software identifies the visual differences between the different blood components or abnormalities while relying on characteristics such as intensity, size, shape, fluorescence intensity, and morphology. Hemoglobin is measured by a unique channel in the device that measures the absorbance of undiluted whole blood in four wavelengths. The technique is based on an absorbance optical measurement through a small volume cavity with a short light path.

The Sight OLO device provides complete blood count information with 5-part differentials for white blood cell types. Specifically, the CBC parameters measured by the Sight OLO device are listed below and include: White Blood Cell Count (WBC), Red Blood Cell Count (RBC), Hemoglobin (HGB), Hematocrit (HCT), Mean Cell Volume (MCV), Mean Cell Hemoglobin (MCH), Mean Cell Hemoglobin Concentration (MCHC), RBC Distribution Width (RDW), Platelet Count (PLT), Neutrophil Percent and Count (NEUT%/#), Lymphocyte Percent and Count (LYMPH %/#), Monocyte Percent and Count (MONO %/#), Eosinophil Percent and Count (EOS%/#), and Basophil Percent and Count (BASO%/#).

C Instrument Description Information:

1. Instrument Name:

   Sight OLO

2. Specimen Identification:

Specimen identification is performed by use of a barcode reader or manually typing the sample ID on the Sight OLO screen.

3. Specimen Sampling and Handling:

The Sight OLO device can be used with either non-anticoagulated fingertip samples or capillary and venous anticoagulated whole blood samples collected in K_2EDTA tubes. Capillary blood sampling is performed by routine finger prick puncture following each user facility's standard guidelines. Per the Operator's Manual, fingertip samples are collected directly from the fingertip into the Sight OLO test kit microcapillaries. Venous and capillary whole blood samples are collected into K_2EDTA tubes or microtubes (respectively) using each user facility's standard procedure. Venous and capillary whole blood should be sufficiently mixed and stored at room temperature for less than eight hours before use.

4. Calibration:

The Sight OLO device is factory calibrated prior to shipping to the end user, and no further calibration is needed. The calibration of Sight OLO is traceable to the reference methods described in CLSI H26-A2.

5. Quality Control:

Whole blood quality control material OLO Control (three levels: high, medium, low) provided by R&D Systems (Minneapolis, MN) is available for the Sight OLO to monitor the performance of the analyzer. It is a stabilized whole blood matrix designed for statistical process control of the Sight OLO.

Quality control range limits are downloaded automatically by an internet connection (or configured locally by scan of QR codes printed on Quality Control product insert). Lot expiration and results validity checks are done using the instrument software via the user interface.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Sight OLO

B Predicate 510(k) Number(s):
K190898

C Comparison with Predicate(s):

Device & Predicate Device(s):	K211840	K190898
Device Trade Name	**Sight OLO**	**Sight OLO**
General Device Characteristic		

Device & Predicate Device(s):	K211840	K190898
Similarities		
Intended Use/Indications for Use	Sight OLO is a quantitative multi-parameter automated hematology analyzer intended for in vitro diagnostic use in screening capillary or venous whole blood samples collected in K2EDTA blood collection tubes, or fingertip samples collected using the Sight OLO test kit microcapillary tubes. When used with the Sight OLO cartridge, the Sight OLO utilizes computer imaging and computer vision algorithms to enumerate the following CBC parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, NEUT%/#, LYMPH %/#, MONO%/#, EO%/#, and BASO%/#. The Sight OLO is indicated for use by clinical laboratories to identify and classify one or more of the formed elements of blood in children 3 months and above, adolescents and adults.	Sight OLO is a quantitative multi-parameter automated hematology analyzer intended for in vitro diagnostic use in screening capillary or venous whole blood samples collected in K2EDTA blood collection tubes, or fingertip samples collected using the Sight OLO test kit microcapillary tubes. When used with the Sight OLO cartridge, the Sight OLO enumerates the following CBC parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, NEUT%/#, LYMPH %/#, MONO%/#, EO%/#, and BASO%/#. The Sight OLO is indicated for use in clinical laboratories to identify and classify one or more of the formed elements of blood in children 3 months and above, adolescents and adults.
Components	• Scanning and analyzing device (include microscope) • Test kit (including a disposable cartridge, a Microsafe microcapillary tube, a dropper cap containing dried reagents and attached to another microcapillary tube and a mixing bottle containing liquid diluent)	Same
Test Parameters	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, NEUT%/#, LYMPH %/#, MONO %/#, E0%/#, and BASO%/#	Same

Device & Predicate Device(s):	K211840	K190898
Analysis modes	Whole blood (capillary and venous)	Same
Specimen collection	Either capillary and venous anticoagulated whole blood samples collected into K2EDTA microtubes / tubes, or capillary samples collected directly from the fingertip into the OLO test kit micro-capillary tubes	Same
Sample volume	17 µL	Same
Calibration / Quality Control	Factory calibrated Optional control kit OLO Control (3 levels) will be provided to user (used if needed)	Factory calibrated Optional control kit CBC-OPT (3 levels) will be provided to user (used if needed)
General Device Characteristic Differences		
Software version	2.57b	2.29.4

VI Standards/Guidance Documents Referenced:

ASTM D7386-16, Standard Practice for Performance Testing of Packages for Single Delivery Systems [5-113]
CLSI EP09-A3: Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Third Edition [7-296]
CLSI H20-A2, Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard – Second Edition [7-165]
CLSI H26-A2, Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard – Second Edition [7-210]
CLSI EP25-A, Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline [7-235]
IEC 62304-2006, Medical device software - Software life-cycle processes [13-79]
IEC 62366, Medical devices – Application of usability engineering to medical devices [5-129]
ISO 14971-2019, Medical devices - Application of risk management to medical devices [5-125]
ISO 15223-1-2016, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1 general requirements [5-117]

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Refer to K190898

2. Linearity:

   Refer to K190898

3. Analytical Specificity/Interference:

   Refer to K190898

   Deoxyhemoglobin

   Since the previous clearance of the Sight OLO, an additional interferent, deoxyhemoglobin, has been evaluated. The purpose of this study was to characterize the susceptibility of the Sight OLO device to low blood oxygen saturation (i.e. lack of oxygen as an interferent) as a potential endogenous interfering substance. The study was conducted using the same protocol used previously in K190898. A total of 14 normal fresh venous whole blood samples were used. Each sample was scanned three times (2 replicates each time) on each of three Sight OLO devices. Each sample was scanned one time after undergoing mixing procedure designed to ensure complete oxygen saturation of the sample (O2Hb > 90%), one time under target reduced oxygen saturation (O2Hb 20-30%), and one time after resaturation (O2Hb > 90%). The first replicate scan under target reduced oxygen saturation and the first replicate scan after resaturation of each sample were used in the analysis. For each sample, the bias was calculated for the following measurands: RBC, WBC, HGB, HCT and PLT, which was determined by the differences between the samples with the interference introduced (reduced oxygen saturation; O2Hb within 20-30%) versus the paired control samples without the interference (full oxygen saturation; O2Hb >90%). Overall, the result showed that there was no interference caused by reduction of oxyhemoglobin to 25% for the following Sight OLO measurands: RBC, WBC, HGB, HCT, and PLT.

4. Assay Reportable Range:

   Refer to K190898

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Sample Stability and Transportation studies – Refer to K190898

   Test Kit Shelf-Life Stability

   An ongoing stability study of the Test Kit following the same protocol described in K190898 has now reached the 18-month time point. The purpose of the real-time stability study is to establish the shelf-life stability of the Sight OLO TK1 test kit when it is stored at its recommended storage conditions (18–26˚C). Three lots of test kits were assessed for functional and analytical tests on no more than five Sight OLO instruments. Each test kit lot was stored at recommended temperature and tested at defined time points (4, 8, 12, 13, 18, 24, 26, 30, 36, 38 months), for a total of 11 time points per lot, including baseline (manufacturing lot release served as time zero baseline). Current results support a shelf-life

stability claim of 18 months from time of production when stored at the recommended temperature (18–26ºC).

Device Calibration Stability

An ongoing calibration stability study of the Sight OLO following the same protocol described in K190898 submission has reached a 15-month time point. The purpose of the study was to establish the calibration stability of the Sight OLO over time. A total of 1,177 samples collected for the method comparison study were analyzed on 3 Sight OLO and 3 Sysmex XN-Series instruments at 3 clinical sites. Sample results within the 5 to 95 percentile range per measurand (RBC, HGB, HCT, MCH, PLT, WBC, and MCV) were included in the analysis and the relative errors of the Sight OLO to the Sysmex XN-Series were computed per sample per measurand. Linear regression of the relative error versus the days since the first samples was analyzed along with the 95% confidence bands were plotted and the results compared to pre-defined acceptance criteria. Current results support a calibration stability claim of 15 months.

6. Detection Limit:

   Refer to K190898

7. Assay Cut-Off:

   Not applicable

8. Accuracy (Instrument):

   Not applicable

9. Carry-Over:

   Not applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:
   A method comparison study using 700 pediatric and adult samples covering the analytical measurement range from three US sites was conducted. Both normal and pathological samples were included in the assessment. The pathological samples included the following conditions: acute inflammation, bacterial and viral infections, aplastic anemia, acute and chronic leukemias (lymphocytic or myelocytic), multiple myeloma (plasma cell leukemia), microcytic anemia, normocytic anemia, macrocytic anemia, hemoglobinopathies, thalassemia, iron and folate deficiencies and giant platelets. The collected samples covered an age range of 3 months to 94 years old, 32% of which were pediatric samples (3M-21Y). The study population included 365 males (52%) and 335 females (48%).

   Passing-Bablok regression analysis was performed for each measurand with results from the Sight OLO device against the results from the Sysmex XN-Series Hematology Analyzer. For

each regression analysis, the slope, intercept and the 95% two-sided confidence interval (CI) around the slope and intercept were calculated, as well as the correlation coefficient. The overall bias was calculated as the median of differences, where differences were taken either as absolute or relative according to the nature of data. In addition, the predicted bias and its 95% CI at the medical decision points were calculated for WBC, HGB and PLT.

The analysis for the method comparison study was conducted on the data from each of the three sites and all sites combined, and only the results of the latter were compared to the acceptance criteria. The results showed that all measurands met the prespecified acceptance criteria for correlation, bias, slope, intercept (and the 95% two-sided confidence interval (CI) around the slope and intercept). Overall, the method comparison results demonstrate that, like the original cleared Sight OLO, the Sight OLO with updated algorithms generates comparable results to the predicate Sysmex XN-Series device.

Results Summary: Sight OLO vs. Sysmex XN-Series – All Sites Combined

Measurand	N	Results Range	Correlation Coefficient (r)	Slope (95% CI)	Intercept (95% CI)	Median Bias	Median Relative Bias (%)
WBC $x10^3/\mu L$	662	0.31 to 98.77	0.997	1.016 (1.008, 1.024)	0.014 (-0.025, 0.067)	0.11	1.92%
RBC $x10^6/\mu L$	674	1.86 to 7.29	0.991	1.019 (1.008, 1.029)	0.09 (0.045, 0.13)	0.16	4.07%
PLT $x10^3/\mu L$	642	21.0 to 1026.0	0.984	1 (0.989, 1.016)	9.00 (5.981, 11.236)	9	4.52%
HGB g/dL	694	4.9 to 21.2	0.99	1.03 (1.019, 1.041)	-0.02 (-0.144, 0.11)	0.3	2.86%
HCT %	675	15.2 to 63.7	0.983	1.029 (1.013, 1.044)	-0.569 (-1.147, 0.007)	0.5	1.33%
MCV fL	675	57.3 to 121.2	0.941	0.888 (0.862, 0.915)	7.55 (5.192, 9.855)	-2.3	-2.61%
RDW %	643	10.6 to 29.4	0.941	1 (0.98, 1.034)	-0.1 (-0.593, 0.176)	-0.1	-0.77%
MCH pg	670	14.9 to 42.0	0.976	1 (0.987, 1.01)	-0.4 (-0.677, -0.002)	-0.4	-1.34%
MCHC g/dL	670	26.0 to 36.6	0.687	0.69 (0.636, 0.75)	10.77 (8.775, 12.545)	0.5	1.47%
NEUT%	558	1.1 to 96.7	0.988	0.995 (0.983, 1.008)	0.93 (0.15, 1.704)	0.6	0.99%
NEUT# $x10^3/\mu L$	547	0.02 to 52.65	0.996	1.023 (1.013, 1.033)	0.025 (-0.002, 0.061)	0.12	3.22%
LYMPH%	581	0.9 to 98.9	0.991	1 (0.992, 1.013)	0.9 (0.534, 1.063)	0.9	3.92%
LYMPH# $x10^3/\mu L$	569	0.02 to 50.06	0.995	1.031 (1.016, 1.047)	0.049 (0.023, 0.074)	0.1	6.28%
MONO%	582	0.0 to 35.6	0.926	0.909 (0.872, 0.947)	-0.127 (-0.434, 0.199)	-0.9	-10.81%

Results Summary: Sight OLO vs. Sysmex XN-Series – All Sites Combined							
Measurand	**N**	**Results Range**	**Correlation Coefficient (r)**	**Slope (95% CI)**	**Intercept (95% CI)**	**Median Bias**	**Median Relative Bias (%)**
MONO# $x10^3/\mu L$	570	0.0 to 7.89	0.947	1.0 (0.97, 1.024)	-0.05 (-0.065, -0.035)	-0.05	-9.51%
EOS%	535	0.0 to 33.3	0.978	1.0 (1.0, 1.043)	0.2 (0.106, 0.2)	0.2	11.76%
EOS# $x10^3/\mu L$	522	0.0 to 4.24	0.98	1.034 (1.0, 1.083)	0.0 (0.008, 0.01)	0.01	14.28%
BASO%	538	0.0 to 3.1	0.658	1.333 (1.214, 1.5)	-0.2 (-0.25, -0.129)	0	-0.01%
BASO# $x10^3/\mu L$	525	0.0 to 0.47	0.646	1.333 (1.2, 1.5)	-0.013 (-0.015, -0.008)	0	-0.05%

The predicted bias and its 95% CI at the medical decision points were within the pre-defined acceptance criteria for individual sites as well as all sites combined.

Medical Decision Point	Site	Bias	95% CI
WBC, $2x10^3/\mu L$	Site 1	0.03	(-0.04, 0.12)
	Site 2	-0.08	(-0.15, 0.08)
	Site 3	0.03	(-0.07, 0.13)
	All sites	0.03	(-0.15, 0.07)
HGB, 6 g/dL	Site 1	0.5	(0.34, 0.66)
	Site 2	0.1	(0.00, 0.20)
	Site 3	0.25	(0.2, 0.46)
	All sites	0.3	(0.2, 0.55)
HGB, 10 g/dL	Site 1	0.2	(0.00, 0.3)
	Site 2	0.1	(0.00, 0.27)
	Site 3	0.00	(-0.17, 0.37)
	All sites	0.0	(0.0, 0.2)
PLT, $50x10^3/\mu L$	Site 1	4.0	(0.34, 15.32)
	Site 2	4.5	(0.65, 7.7)
	Site 3	8.0	(5.34, 13.66)
	All sites	5.5	(2.34,10.99)

Concordance Analysis at Medical Relevant Points

The results of the method comparison studies demonstrated there were constant bias and proportional bias for some measurands. Therefore, for each medical relevant point, a truth table with Bayesian analysis was performed to calculate the positive percent agreement (PPA), negative percent agreement (NPA) and overall percent agreement (OPA) between the Sight OLO and the Sysmex XN-Series Analyzer (all tables shown below). Based on the expert clinician review, none of the observed discordances would affect clinical decision making for the specific patients.

PLT at 50 x 10^3/µL		Sysmex XN		
		Positive (Abnormal)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	30	0	30
	Negative (Normal)	2	609	611
	Total	32	609	641
		PPA 93.75%	NPA 100.0%	OPA 99.7%

Thrombocytosis (PLT > 450 x 10^3/µL)		Sysmex XN		
		Positive (Abnormal)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	42	8	50
	Negative (Normal)	1	590	591
	Total	43	598	641
		PPA 97.7%	NPA 98.7%	OPA 98.6%
Thrombocytopenia (PLT < 150 x 10^3/µL)		Sysmex XN		
		Positive (Abnormal)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	101	4	105
	Negative (Normal)	8	524	532
	Total	110	531	637
		PPA 92.7%	NPA 99.2%	OPA 98.1%

Neutrophilia, adults (22+ years): > 7,500 neutrophils /µL		Sysmex XN		
		Positive (Abnormal)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	62	7	69
	Negative (Normal)	1	309	310
	Total	63	316	379
		PPA 98.4%	NPA 97.8%	OPA 97.9%
Neutrophilia, children (<22 years): > 8,500 neutrophils /µL		Sysmex XN		
		Positive (Abnormal)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	15	0	15
	Negative (Normal)	0	153	153
	Total	15	153	168
		PPA 100%	NPA 100%	OPA 100%

Lymphocytosis, adults and adolescents (12+ years): > 4,500 lymphocytes /µL		Sysmex XN		
		Positive (Abnormal)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	10	0	10
	Negative (Normal)	0	478	478
	Total	10	479	488

		PPA 100%	NPA 100%	OPA 100%
Lymphocytosis, young children (<12 years): > 10,000 lymphocytes /µL		Sysmex XN		
		Positive (Abnormal)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	0	0	0
	Negative (Normal)	0	77	77
	Total	0	77	77
		PPA N/A	NPA 100%	OPA 100%

Monocytosis, adults and adolescents (12+ years): > 800 – 1300 monocytes /µL		Sysmex XN			
		Positive (Abnormal)	Ambiguous (within range)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	31	3	1	35
	Ambiguous (within range)	9	56	9	74
	Negative (Normal)	0	31	353	384
	Total	40	90	363	493
		PPA 100%		NPA 99.7%	OPA 99.7%
Monocytosis, young children (<12 years): > 1000 – 1500 monocytes /µL		Sysmex XN			
		Positive (Abnormal)	Ambiguous (within range)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	7	0	0	7
	Ambiguous (within range)	1	3	2	6
	Negative (Normal)	0	2	62	64
	Total	8	5	64	77
		PPA 100%		NPA 100%	OPA 100%

Eosinophilia, adults (22+ years): > 400 eosinophils /µL		Sysmex XN		
		Positive (Abnormal)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	18	6	24
	Negative (Normal)	2	323	325
	Total	20	329	349
		PPA 90.0%	NPA 98.2%	OPA 97.7%
Eosinophilia, pediatrics (<22 years): > 700 eosinophils /µL		Sysmex XN		
		Positive (Abnormal)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	5	0	5
	Negative (Normal)	0	166	166
	Total	5	166	171

		PPA 100%	NPA 100%	OPA 100%

Basophilia: > 1% – 2% basophils		Sysmex XN			
		Positive (Abnormal)	Ambiguous (within range)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	5	11	1	17
	Ambiguous (within range)	1	30	48	79
	Negative (Normal)	0	26	416	442
	Total	6	67	465	538
		PPA 100%		NPA 99.8%	OPA 99.8%

Severe Leukopenia: < 2,000 WBC/µL		Sysmex XN		
		Positive (Abnormal)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	41	4	45
	Negative (Normal)	0	614	614
	Total	41	618	659
		PPA 100%	NPA 99.4%	OPA 99.4%

Neutropenia: < 1,000 neutrophils /µL		Sysmex XN		
		Positive (Abnormal)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	19	4	23
	Negative (Normal)	2	522	524
	Total	21	526	547
		PPA 90.5%	NPA 99.2%	OPA 98.9%

Severe Neutropenia: < 500 neutrophils /µL		Sysmex XN		
		Positive (Abnormal)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	3	0	3
	Negative (Normal)	3	541	543
	Total	6	541	547
		PPA 50%	NPA 100%	OPA 99.5%

Lymphocytopenia: < 1,000 lymphocytes /µL		Sysmex XN		
		Positive (Abnormal)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	96	4	100
	Negative (Normal)	20	446	466
	Total	116	450	566
		PPA 82.8%	NPA 99.1%	OPA 95.8%

Monocytopenia: < 100 – 200 monocytes /µL		Sysmex XN			
		Positive (Abnormal)	Ambiguous (within range)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	6	4	0	10
	Ambiguous (within range)	2	8	13	23
	Negative (Normal)	0	2	535	537
	Total	8	14	548	570
		PPA 100%		NPA 100%	OPA 100%

Moderate anemia, 5+ years: HGB < 11 g/dL		Sysmex XN		
		Positive (Abnormal)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	219	1	220
	Negative (Normal)	9	407	416
	Total	228	408	636
		PPA 96.1%	NPA 99.8%	OPA 98.4%
Moderate anemia, <5 years: HGB < 10 g/dL		Sysmex XN		
		Positive (Abnormal)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	19	1	20
	Negative (Normal)	0	30	30
	Total	19	31	50
		PPA 100%	NPA 96.8%	OPA 98.0%

Severe anemia, 22+ years: HGB < 8 g/dL		Sysmex XN		
		Positive (Abnormal)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	45	0	45
	Negative (Normal)	10	411	421
	Total	55	411	466
		PPA 81.8%	NPA 100%	OPA 97.9%
Severe anemia, pediatrics: HGB < 6 g/dL		Sysmex XN		
		Positive (Abnormal)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	1	0	1
	Negative (Normal)	0	219	219
	Total	1	219	220
		PPA 100%	NPA 100%	OPA 100%

Polycythemia, females: HGB > 16.5 g/dL		Sysmex XN		
		Positive (Abnormal)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	4	3	7
	Negative (Normal)	0	327	327
	Total	4	330	334

		PPA 100%	NPA 99.1%	OPA 99.1%
Polycythemia, males: HGB > 18.5 g/dL		Sysmex XN		
		Positive (Abnormal)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	3	4	7
	Negative (Normal)	0	352	352
	Total	3	356	359
		PPA 100%	NPA 98.9%	OPA 98.9%

2. Matrix Comparison:

A capillary vs. venous matrix comparison study consisting of 67 normal and pathological paired capillary K2EDTA whole blood and venous K2EDTA whole blood specimens were used. Paired specimens collected from the same individuals were assayed in duplicate on the OLO device to compare performance between capillary whole blood samples and venous whole blood samples, and the results were analyzed for all applicable measurands. Analysis included Passing-Bablok regression analysis per measurand (Bland Altman plots, slope, intercept, with 95% confidence intervals, correlation coefficient, and % bias), between the average of two venous whole blood sample repeats and the average of two capillary whole blood sample repeats from the same individual on the Sight OLO. Overall, the study results from the Sight OLO device show comparable performance characteristics for K2EDTA capillary and K2EDTA venous whole blood samples.

C Clinical Studies:

1. Clinical Sensitivity:

A flagging study was conducted, comparing the Sight OLO to manual light microscopy for normal (no flags) and abnormal (flags present) for 108 normal samples and 100 abnormal samples at three clinical study sites. Three blood films were prepared for each sample. Two qualified morphology examiners evaluated one of the three blood films. In each blood film a 200-cell count was performed for a total of 400 cells for the two examiners together. Two types of abnormalities were evaluated: (1) distributional abnormal samples, which are samples where the quantity of at least one of the WBC diffs% parameters reside outside of the normal concentrations, and (2) morphological abnormal samples, which are samples that contain atypical forms of the normal cell types in ordinary blood samples. Three Sight OLO instruments were used for the study (one at each site) and one lot of Sight OLO test kits was used. Overall, the flagging capability of the Sight OLO device met the pre-defined acceptance criteria for both overall sensitivity and specificity.

Distributional Flagging		Reference Method – Manual Microscopy		
		Positive (Abnormal)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	83	6	89
	Negative (Normal)	11	108	119
	Total	94	114	208

	%	95% CI	
Sensitivity (PPA)	88.3%	80.0%	94.0%
Specificity (NPA)	94.7%	88.9%	98.0%
Overall Agreement	91.8%	87.2%	95.2%

Distributional Flagging (with flagged WBC-diff removed)		Reference Method – Manual Microscopy		
		Positive (Abnormal)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	55	3	58
	Negative (Normal)	9	100	109
	Total	64	103	157

	%	95% CI	
Sensitivity (PPA)	85.9%	75.0%	93.4%
Specificity (NPA)	97.1%	91.7%	99.4%
Overall Agreement	92.8%	87.8%	96.2%

Morphological Flagging		Reference Method – Manual Microscopy		
		Positive (Abnormal)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	21	20	41
	Negative (Normal)	1	166	167
	Total	22	186	208

	%	95% CI	
Sensitivity (PPA)	95.5%	77.2%	99.9%
Specificity (NPA)	89.3%	83.4%	93.3%
Overall Agreement	89.9%	85.0%	93.6%

Overall Flagging Performance		Reference Method – Manual Microscopy		
		Positive (Abnormal)	Negative (Normal)	Total
Sight OLO	Positive (Abnormal)	6	0	10
	Negative (Normal)	0	535	537
	Total	8	548	570

	%	95% CI	
Sensitivity (PPA)	91.0%	83.6%	95.8%
Specificity (NPA)	92.6%	85.9%	96.8%
Overall Agreement	91.8%	87.2%	95.2%

2. Clinical Specificity:

   See Clinical Sensitivity above.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

Refer to K190898

F Other Supportive Instrument Performance Characteristics Data:

Refer to K190898

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.