May 9, 2022

S.D. Sight Diagnostics Ltd.
% Janice Hogan
Regulatory Counsel
Hogan Lovells US LLP
1735 Market Street Suite 2300
Philadelphia, Pennsylvania 19103

Re: K211840
Trade/Device Name: Sight OLO
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: Class II
Product Code: GKZ
Dated: June 14, 2021
Received: June 14, 2021

Dear Janice Hogan:

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.
Branch Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
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 on last page

510(k) Number *(if known)*

K211840

Device Name

Sight OLO

Indications for Use *(Describe)*

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 %/#, EOS%/#, 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.

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

X 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

S.D. Sight Diagnostics 's Sight OLO

Submitter

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Date Prepared: May 6, 2022

Name of Device:

Sight OLO

Common or Usual Name:

Automated Hematology Analyzer

Classification:

21 CFR 864.5220, Class II, Product Code: GKZ

Predicate Devices

Predicate Device:	Sight OLO (K190898)
Reference Device:	Sysmex® (XN-10, XN-20) Automated Hematology Analyzers (K112605)

Device Description

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. Using dedicated staining, the proposed platform provides complete blood count analysis. The Sight OLO is a compact device, designed to be automated and simple to operate, to enable rapid testing and analysis. The Sight OLO consists of a scanning and analyzing device and a CBC test kit, including a disposable cartridge and sample preparation tools. The disposable cartridge containing the blood sample is loaded into the device through the loading slot. The device is operated through the touch screen interface.

The Sight OLO provides complete blood count information with 5-part differentials for white blood cell types. Specifically, the CBC parameters measured by the Sight OLO are listed below and include: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, NEUT%/#,

LYMPH %/#, MONO %/#, EOS%/# and BASO%/#. In addition, the Sight OLO signals specific WBC abnormal cases by flagging the sample.

Intended Use / Indications 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.

Summary of Substantial Equivalence

The subject Sight OLO device is a modification to the previous version of Sight OLO that was cleared in K190898. Both devices are quantitative, multiparameter, automated in vitro diagnostic hematology analyzers. Both devices screen whole blood samples collected from venous and/or capillary blood. The same parameters are encompassed by both devices. The components and functions of both devices are the same. Both devices include a scanning and analyzing device (including microscope) and a test kit (including a disposable cartridge, a Microsafe micro-capillary tube, a dropper cap containing dried reagents and attached to another micro-capillary tube and a mixing bottle containing liquid diluent). Both devices incorporate the same steps necessary for blood analysis within the device design. Both devices are factory calibrated prior to shipping to the end user, and no further calibration is needed. Whole blood quality control material is available for both devices. Both devices include flagging capabilities to detect and signal abnormal conditions.

There have been several minor modifications to the device since the previous clearance. The primary updates include minor modifications to analysis algorithms performed in order to increase the proportion of actionable results by reducing the sample rejection rate, improving the flagging specificity, and reducing the parameter invalidation rate following a flag. None of these changes affect the principles of operations, scanning hardware or scanning algorithms. These minor modifications do not raise any different questions of safety or effectiveness. In addition, verification and repeated performance testing confirmed that the updated device continues to perform in accordance with its specifications and is as safe and as effective as the predicate.

Performance Data

The performance of the Sight OLO device has been evaluated in a battery of analytical and clinical tests, as previously provided in K190898. As the changes made to the device were primarily to the OLO algorithm around small refinements to the WBC-differential flagging invalidation logic, and do not change the device's scanning mechanism or the CBC parameters

specifications, the majority of the studies conducted on previously cleared Sight OLO were not impacted by these changes. A subset of tests were re-run using the updated algorithm to support the substantial equivalence between the modified device and the previously cleared device version, as summarized below.

Method comparison study with reference device (CLSI H20-A2, H26-A2 and EP09-A3)

Method comparison studies were conducted to assess the performance of the Sight OLO device, compared to the reference device (Sysmex XN-Series Hematology Analyzer, K112605). The samples previously collected in K190898 were re-run with the updated algorithm of the subject device. The testing design was based on the test methods outlined in CLSI H20-A2, CLSI H26-A2 and CLSI EP09-A3, and is consistent with the testing design conducted for other whole blood analysis devices, including the reference Sysmex XN cleared in K112605. The testing was conducted at three (3) US sites using a total of 700 residual clinical K2EDTA whole blood samples that were collected from both adults (≥22 years old) and pediatric patients (3 months to 21 years old). All samples were run in singlet on the reference Sysmex XN and within 2 hours in singlet on the Sight OLO device.

The studies included normal and pathological samples to assess the OLO performance across the analytical measuring range (AMR) as well as around medical decision points. 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 samples collected cover an age range of 3 months to 94 years old, 32% of samples are pediatric samples (3M-21Y), and the study population included 365 males (52%) and 335 females (48%).

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). A summary of the results is presented in the table below:

Method Comparison Results

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%
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%

Test Kit Shelf-Life

The shelf life for the test kit is set at 16 months at the recommended temperature, based on testing that included stability verification at 18 months after release. Functional and analytical tests were conducted and results met the predefined acceptance criteria.

Flagging study (CLSI H20-A2)

The samples previously collected in K190898 were re-run with the updated algorithm of the subject device. Flagging studies were conducted, where Sight OLO was compared to manual light microscopy for normal (no flags and normal distribution) and abnormal (morphological flags present or distributionally abnormal) samples, including over 200 samples at 3 clinical study sites. Three blood films were prepared for each sample. Two qualified morphology examiners evaluated one of the three blood films (i.e., Reader A read slide A and Reader B read slide B). In each blood film a 200 cells count was performed for a total of 400 cells count for the two examiners together. The third blood film was saved for reading by a third qualified morphology examiner (i.e., arbitrator) in the event that there was disagreement between Reader A and Reader B. Two types of abnormalities were evaluated: (1) distributional abnormal samples, which are samples where the quantity of at least one of the WBC diff % parameters resides outside of the normal concentrations, and (2) morphological abnormal samples, which are samples that contain atypical forms of the normal cell types contained in ordinary blood samples. The manual microscopy readings were compared to the results obtained with the Sight OLO for the same patient blood sample.

The overall flagging capabilities of the Sight OLO device met the predefined acceptance criteria for both sensitivity and specificity, as seen in the table below.

Flagging Capability

Sensitivity (PPA)	91.0%
Specificity (NPA)	92.6%
Overall Agreement	91.8%

Conclusions

The Sight OLO and its predicate device have the same intended use as well as similar indications for use, technological characteristics, and principles of operation. The differences between the devices do not present new issues of safety or effectiveness. Furthermore, performance testing demonstrated comparable performance characteristics between the Sight OLO and its predicate. Thus, the Sight OLO is substantially equivalent to its predicate device.