March 26, 2025

Kent Imaging Inc.
Hitalo Arume
Regulatory Affairs and Quality Assurance Manager
Suite 300, 1210 8 Street SW
Calgary, AB T2R 1L3
Canada

Re: K242669
Trade/Device Name: SnapshotGLO (KB100)
Regulation Number: 21 CFR 878.4550
Regulation Name: Autofluorescence Detection Device For General Surgery And Dermatological Use
Regulatory Class: Class II
Product Code: QJF, FXN
Dated: March 17, 2025
Received: March 17, 2025

Dear Hitalo Arume:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2025.03.26 16:27:24 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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)*
K242669

Device Name
SnapshotGLO (KB100)

Indications for Use *(Describe)*
The SnapshotGLO is a handheld imaging tool that allows clinicians diagnosing and treating skin wounds, at the point of care, to
(i) View and digitally record images of a wound,
(ii) Measure and digitally record the size of a wound, and
(iii) View and digitally record images of fluorescence emitted from a wound when exposed to an excitation light.
The fluorescence image, when used in combination with clinical signs and symptoms, has been shown to increase the likelihood that clinicians can identify wounds containing bacterial loads >104 CFU per gram as compared to examination of clinical signs and symptoms alone. The SnapshotGLO device should not be used to rule-out the presence of bacteria in a wound.
The SnapshotGLO does not diagnose or treat skin wounds.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

March 25, 2025

510(k) Number: K242669

Device Name: SnapshotGLO (KB100)

Submittal Information:

Post-approval contact:
Hitalo Arume

Kent Imaging Inc.
Suite 300, 1210 8 Street SW
Calgary, AB CANADA T2R 1L3

Phone: 403-455-7610
Fax: 877-664-5450

Name of the Device

SnapshotGLO

Device Classification and Product Code

Autofluorescence detection device, 21 CFR 878.4550, Class II, QJF

Tape, Camera, Surgical, 21 CFR 878.4160, Class I, FXN

Legally Marketed Predicate Device

Device Name: MolecuLightDX

510(k) Number: K211901

SnapshotGLO (KB100) information

Indications for Use

The SnapshotGLO is a handheld imaging tool that allows clinicians diagnosing and treating skin wounds, at the point of care, to

i. View and digitally record images of a wound,
ii. Measure and digitally record the size of a wound, and
iii. View and digitally record images of fluorescence emitted from a wound when exposed to an excitation light.

The fluorescence image, when used in combination with clinical signs and symptoms, has been shown to increase the likelihood that clinicians can identify wounds containing bacterial loads $>10^4$ CFU per gram as compared to examination of clinical signs and symptoms alone. The SnapshotGLO device should not be used to rule-out the presence of bacteria in a wound.

The SnapshotGLO does not diagnose or treat skin wounds.

Device Description

SnapshotGLO is a medical device that operates like a camera. It is a point-of-care, wound imaging device. This device is a non-contact imaging device wherein the wound images are captured from a height of ~12 cm using 395 nm LEDs and a white LED to produce a resultant fluorescence image that aids in visualising the bacteria on the wound and a colour-based "RGB" image or clinical image. Resultant images are viewed on the 7-inch touchscreen display.

SnapshotGLO is based on autofluorescence imaging technology and uses native fluorescence of bacteria to determine the presence of bacterial bioburden and displays a two-dimensional, colour-coded highlight of bioburden presence on the wounds.

SnapshotGLO is a handheld imaging tool that allows clinicians diagnosing, monitoring and treating skin wounds at the point of care with the help of the following features:

- View and digitally record images of a wound,
- Measure and digitally record the size of a wound, and
- View and digitally record images of fluorescence emitted from a wound when exposed to an excitation light

SnapshotGLO consists of:

- SnapshotGLO device
- Medical grade adapter
- User Manual
- Quick Start Guide

SnapshotGLO is intended for wound care applications as an adjunct tool that uses autofluorescence to detect tissues or structures. The fluorescence image, when used in combination with clinical signs and symptoms, has been shown to increase the likelihood that clinicians can identify wounds containing high bacteria bioburden compared to clinical symptoms alone. SnapshotGLO should not be used to rule-out the presence of bacteria in a wound. This device is not intended to provide a diagnosis.

Fundamental Principles

SnapshotGLO operates using autofluorescence imaging technology. When exposed to 395 nm excitation light, naturally occurring bacterial compounds emit fluorescence in the visible spectrum (400–700 nm). This emitted light is captured by the device to generate fluorescence images that highlight areas of potential bacterial presence. When interpreted alongside clinical signs and symptoms, these images can assist clinicians in identifying wounds with high bacterial bioburden. The device also captures white light images and enables wound measurement, with results displayed on an integrated touchscreen for clinical review and documentation.

Non-clinical study

Culture Plate Bench Testing:

This nonclinical test aimed to evaluate the efficacy of the SnapshotGLO device in detecting bacterial fluorescence after ultraviolet excitation and compare it with the predicate device, MoleculightDX. The primary endpoints focused on detecting red fluorescence from porphyrin-producing bacteria, both in mono- and bi-microbial settings, as well as in bacterial biofilms. The secondary endpoints examined the time-series analysis of red fluorescence intensity.

The nonclinical test provided robust evidence that the SnapshotGLO device is substantially equivalent to the MoleculightDX in detecting bacterial fluorescence. The results support the device's effectiveness in clinical settings, confirming its potential for identifying porphyrin-producing bacteria and biofilms in wound care and infection management.

Wound dimensions Testing:

This nonclinical testing discussed a comprehensive comparison of the SnapshotGLO device against the predicate device, MoleculightDX, to assess their equivalence in measuring wound dimensions. The purpose of these tests is to determine whether SnapshotGLO performs similarly to MoleculightDX, supporting a claim of substantial equivalence in the 510(k) submission.

This nonclinical test demonstrates that SnapshotGLO performs comparably to the predicate device, MoleculightDX, in manual wound detection modes. The strong agreement in measurement accuracy and repeatability between the two devices supports the claim of substantial equivalence.

Clinical data

A retrospective clinical study involving 40 patients and two clinical evaluators was conducted to compare the performance of SnapshotGLO and MolecuLightDX, alongside clinical signs and symptoms (CSS). This blinded assessment demonstrated that SnapshotGLO, when used in conjunction with CSS, showed over 88% positive percent agreement and provided improved accuracy (75–82.5%) compared to MolecuLightDX (52.5–65%) when validated against culture results. These findings support the device's substantial equivalence and improved clinical performance.

Substantial Equivalence

The SnapshotGLO (KB100) has the same regulatory information as the predicate device MolecuLightDX (K211901).

Detailed Comparative Features between Devices.

Description	MoleculightDX (Predicate)	SnapshotGLO (Subject)	Notes
Regulation Class	Class II	Class II	Same
Regulation Number	QJF, FXN	QJF, FXN	Same

Description	MoleculightDX (Predicate)	SnapshotGLO (Subject)	Notes
Product Classification	21 CFR 878.4550 21 CFR 878.4160	21 CFR 878.4550 21 CFR 878.4160	Same
Classification Name	Autofluorescence detection device for general surgery and dermatological use	Autofluorescence detection device for general surgery and dermatological use	Same
Accessories	Dark drape/adapter/power cable	Drape/adapter/power cable	Same
Intended use	Intended for general surgery and dermatological use as an adjunct tool that uses autofluorescence to detect tissues or structures. This device is not intended to provide a diagnosis.	Intended for general surgery and dermatological use as an adjunct tool that uses autofluorescence to detect tissues or structures. This device is not intended to provide a diagnosis.	Same
Indications for use	The MolecuLightDX is a handheld imaging tool that allows clinicians diagnosing and treating skin wounds, at the point of care, to i) View and digitally record images of a wound, ii) Measure and digitally record the size of a wound, and iii) View and digitally record images of fluorescence emitted from a wound when exposed to an excitation light. The fluorescence image, when used in combination with clinical signs and symptoms, has been shown to increase the likelihood that clinicians can identify wounds containing bacterial loads $>10^4$ CFU per gram as compared to examination of clinical signs and symptoms alone. The MolecuLightDX device should not be used to	The SnapshotGLO is a handheld imaging tool that allows clinicians diagnosing and treating skin wounds, at the point of care, to i) View and digitally record images of a wound, ii) Measure and digitally record the size of a wound, and iii) View and digitally record images of fluorescence emitted from a wound when exposed to an excitation light. The fluorescence image, when used in combination with clinical signs and symptoms, has been shown to increase the likelihood that clinicians can identify wounds containing bacterial loads $>10^4$ CFU per gram as compared to examination of clinical signs and symptoms alone. The SnapshotGLO device should not be used to rule-out	Same

Description	MoleculightDX (Predicate)	SnapshotGLO (Subject)	Notes
	rule-out the presence of bacteria in a wound. The MolecuLightDX does not diagnose or treat skin wounds.	the presence of bacteria in a wound. The SnapshotGLO does not diagnose or treat skin wounds.	
Target organ	Wounds	Wounds	Same
Patient population	Adult patients	Adult patients	Same
Operating modes	Standard and fluorescence imaging, video and image capture	Autofluorescence and white light imaging	Similar: SnapshotGLO operates in white light and autofluorescence image capture mode only.
Excitation light	405 nm light emitted from light emitting diodes (LED)s	395 nm light emitted from light emitting diodes (LED)s	Similar. Small difference in excitation wavelength.
White LED	MoleculightDX has a white LED which is referred to as a torch.	White LED that covers the visible spectrum (~400-700 nm)	Similar, both devices use white light when capturing RGB images
Emission wavelength	500-545 nm and 600-665 nm	400-700 nm	Similar
Contrast agent	Not required – autofluorescence-based target	Not required – autofluorescence-based target	Same
Infrared Laser Distance Finder Wavelength	940 nm	940 nm	Same
Infrared Laser Distance Finder Peak Power Output	17 mW	17 mW	Same
Working distance	8 – 12 cm (Fluorescence and Standard Imaging) 8 – 20 cm (Measurement Mode)	11- 13 cm from the region of interest for both fluorescence and wound measurement modes	Similar. The slight difference in the imaging distance does not affect the performance of the device.
Optical head	3 camera system	1 RGB camera	Different. Only 1 camera required for autofluorescence and wound dimension measurement.

Description	MoleculightDX (Predicate)	SnapshotGLO (Subject)	Notes
Resolution (focal plane)	8 megapixels	Maximum 12 MP for RGB camera	Similar.
Maximum Frame Rate	30 images/sec	30 images/sec	Same
Camera Bit Depth	8 bits	8 bits for RGB camera	Same
Image size (pixels)	3264 x 2448 pixels	1200x1200 pixels	Similar
Image format	JPEG	JPEG	Same
Software operating system (OS) compatibility	Android 9.1	A customized OS provided by the module manufacturer (Quectel) based on the AOSP of Android 10Q.R8.	Similar. Both devices use an Android-based OS.
Measurement Functionality	Stickerless Wound Measurement: Wound length, width, and area measurements	Stickerless Wound Measurement: Length, Width, and Area measurements	Same
Power Supply	Battery and Wall	Battery and Wall	Same
Display	5.5” AMOLED display	7” LCD display	Similar.
Patient Contacting Materials	Non-patient contacting device	Non-patient contacting device	Same
Sterility	Device non-sterile	Device non-sterile	Same
Electrical Safety	Compliance to IEC 60601-1	Compliance to IEC 60601-1	Same
Mechanical Safety	Compliance to IEC 60601-1	Compliance to IEC 60601-1	Same
Chemical Safety	No chemical delivered or used as part of the system	No chemical delivered or used as part of the system	Same
Standards with which the Device complies	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57 IEC 62471	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57 IEC 62471 IEC 60601-2-22	Similar. The laser module in the ranging sensor is IEC 60601-2-22 certified.
Connectivity	Can be connected to wireless networks	Can be connected to wireless networks	Same

Conclusion

The SnapshotGLO (KB100) has the same intended use, indications for use, and fundamental technological characteristics as the predicate device, MolecuLightDX (K211901). Minor differences in design, such as

excitation wavelength and imaging hardware, do not raise new questions of safety or effectiveness. Non-clinical and clinical performance data support that SnapshotGLO is substantially equivalent to the predicate device for its intended purpose in wound imaging and bacterial fluorescence detection.