November 10, 2020

Kent Imaging
Liz Newell
Director, Clinical Research
804B 16th Ave SW
Calgary, Alberta t2r 0s9
Canada

Re: K201976
Trade/Device Name: SnapshotNIR
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: July 15, 2020
Received: July 16, 2020

Dear Liz Newell:

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); 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,

Purva Pandya
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201976

Device Name
SnapshotNIR

Indications for Use *(Describe)*

SnapshotNIR is intended for use by healthcare professionals as a non-invasive tissue oxygenation measurement system that reports an approximate value of:

- oxygen saturation (StO2),
- relative oxyhemogoblin level (HbO2), and
- relative deoxyhemoglobin (Hb) level

in superficial tissue. SnapshotNIR displays two-dimensional color-coded images of tissue oxygenation of the scanned surface and reports multispectral tissue oxygenation measurements for selected tissue regions.

SnapshotNIR is indicated for use to determine oxygenation levels in superficial tissues.

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.

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510(k) Summary

Snapshot$_{NIR}$ (November 2nd, 2020)

Submittal Information:

Post-approval contact:
Liz Newell
Kent Imaging Inc.
804B 16th Ave SW
Calgary, AB, Canada T2R 0S9

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

Device Name and Classification

Proprietary Name:	Snapshot$_{NIR}$
Common Name:	Tissue Oximeter
Classification Name:	Oximeter, Tissue Saturation (21 CFR 870.2700, Product Code: 74 MUD)
Device Class:	Class II
Classification Panel:	Cardiovascular

Device Description

Snapshot$_{NIR,}$ Model KD204 (K201976), is a modification to the Kent Camera, Model KD203 (K163070). The changes made to create the modified snapshot include modifications to the software. Both devices have similar hardware.

Snapshot$_{NIR}$ is based on multispectral imaging technology and performs spectral analysis at each point in a two-dimensional scanned area producing an image displaying information derived from the analysis. Snapshot$_{NIR}$ determines the approximate values of oxygen saturation (S_tO_2), oxyhemoglobin levels (HbO_2), and deoxyhemoglobin levels (Hb) in superficial tissues and displays a two-dimensional, color-coded image of the tissue oxygenation (S_tO_2).

The camera consists of:

- Camera: Contains light source, camera and touchscreen PC
- Recharger: Used to recharge the camera
- Reference Card: To calibrate the camera

Intended Use

Snapshot$_{NIR}$ is intended for use by healthcare professionals as a non-invasive tissue oxygenation measurement system that reports an approximate value of:

- oxygen saturation (StO_2),
- oxyhemoglobin level (HbO_2), and
- deoxyhemoglobin (Hb) level

in superficial tissue. Snapshot$_{NIR}$ displays two-dimensional color-coded images of tissue oxygenation of the scanned surface and reports multispectral tissue oxygenation measurements for selected tissue regions.

The Snapshot$_{NIR}$ is indicated for use to determine oxygenation levels in superficial tissues.

Comparison with the Predicate Device

Comparative Feature	**Kent Imaging Inc. Modified Snapshot$_{NIR}$-KD204** (K201976)	**Kent Imaging Inc. Predicate Kent Camera – KD203** (K163070)	**Significant Differences**
Indications for Use	The Kent Camera is intended for use by healthcare professionals as a non-invasive tissue oxygenation measurement system that reports an approximate value of oxygen saturation (StO2), oxyhemoglobin level (HbO2), and deoxyhemoglobin (Hb) level in superficial tissue. The Kent Camera displays two-dimensional color-coded images of tissue oxygenation of the scanned surface and reports multispectral tissue oxygenation measurements for selected tissue regions. The Kent Camera is indicated for use to determine oxygenation levels in superficial tissues.	The Kent Camera is intended for use by healthcare professionals as a non-invasive tissue oxygenation measurement system that reports an approximate value of oxygen saturation (StO2), oxyhemoglobin level (HbO2), and deoxyhemoglobin (Hb) level in superficial tissue. The Kent Camera displays two-dimensional color-coded images of tissue oxygenation of the scanned surface and reports multispectral tissue oxygenation measurements for selected tissue regions. The Kent Camera is indicated for use to determine oxygenation levels in superficial tissues.	Same
Measurements	• Oxygen saturation • Oxyhemoglobin level • Deoxyhemoglobin level	• Oxygen saturation • Oxyhemoglobin level • Deoxyhemoglobin level	Same
Method of Measurement	Non-invasive, non-patient contacting imaging head illuminates the surface and receives	Non-invasive, non-patient contacting imaging head illuminates the surface	Same

	returned light	and receives returned light	
	6 wavelengths between 600nm and 1000nm	6 wavelengths between 600nm and 1000nm	Same
	A CMOS image sensor with global shutter is used as the detector	A CMOS image sensor with global shutter is used as the detector	Same
	Spectral analysis at specific wavelengths of light returned from the target tissue	Spectral analysis at specific wavelengths of light returned from the target tissue	Similar – improved signal to noise in modified device
Light Source	LEDs	LEDs	Same
Lens	Corrected and optimized for use from 400nm to 1000nm	Corrected and optimized for use from 400nm to 1000nm	Same
Output Display	• Two-dimensional color-coded map of estimated oxygen saturation • Numeric data	• Two-dimensional color-coded map of estimated oxygen saturation • Numeric data	Same
Power Source	DC (battery-powered)	DC (battery-powered)	Same
Patient Contact	None	None	Same
Control Method	Computer controlled	Computer controlled	Same
Calibration	Preformed at start-up by operator and repeated if operating conditions of camera change to the degree that necessitates recalibration	Preformed at start-up by operator. Performed periodically during extended picture capturing sessions	Similar; Modified device monitors operating conditions and requires recalibration based on changed operating conditions
Sterility	Device is not considered sterile	Device is not considered sterile	Same
Software Language	C#	LabVIEW	Similar; The change in programming languages had no effect on performance. This change does not present any additional safety

			or effectiveness concerns.
Selection Tools	Circle (S_tO_2%) Region/Perimeter (S_tO_2% and cm^2) Line (cm)	Circle (%)	Similar; Modified device displays approximate 2D measures in addition to %S_tO_2
Region of Interest (ROI) Area	Support freehand drawing ROI selection (cm^2)	None	Similar; users can draw a custom region of interest. The change to include freehand ROI drawing had no effect on the performance of the device.
System Components	Camera, Calibration card and recharger	Camera, Calibration card and recharger	Same
Image Format	DICOM	DICOM	Same
Connectivity	Wi-Fi available only when emailing a report	Wi-Fi not enabled	Similar; Wi-Fi only available when emailing reports. The change to turn on Wi-Fi does not affect the performance of the device and does not present any effectiveness concerns or unacceptable risks.
Product lifetime	6 years	6 years	Same

Similarities and Differences

The changes made to create the modified $Snapshot_{NIR}$ are software specific. Both devices have the same hardware (LEDs, image sensor, enclosure) and are the same mechanically. Both cameras use spectral analysis to determine oxygenation levels in near-surface tissues. Both cameras display numeric values of approximate oxygen saturation of the hemoglobin as well as displaying the related approximate oxyhemoglobin and deoxyhemoglobin levels necessary for

the oxygen saturation calculation. Both cameras provide two-dimensional mapping of color-coded oxygenation levels. Both cameras do not come in contact with the patient. Both cameras have the same indications for use and the same fundamental scientific technology.

The modified $Snapshot_{NIR}$ has several software specific differences compared to the predicate Kent Camera. $Snapshot_{NIR}$ application is written in C# where the predicate device was written in LabVIEW. $Snapshot_{NIR}$ has a modified algorithm for calculating S_tO_2. The updated algorithm was implemented to increase the signal to noise ratio and provide better image quality is relies on the same fundamental scientific principles as the predicate algorithm. Lastly, $Snaphot_{NIR}$ has an updated user interface which allows for freehand selection of areas and approximate 2D size measurements and can be connected to a wireless network. The user follows the same workflow for capturing images with the modified device as with the predicate.

Non-Clinical Tests

The modified device went through and passed both internal testing for user and design requirements, as did the predicate device. The modified device compared to the predicate device has no change to the hardware or to the fundamental way it interacts with or configures the hardware therefore although testing wasn't repeated, it is still compliant with the international standards below.

- Electrical safety and essential performance: ANSI/AAMI ES60601-1:2005/(R)2012
- Electromagnetic compatibility: IEC 60601-1-2: 2014

Both the predicate and modified devices are battery (DC) powered. The same battery is used in both devices and it is compliant with the following standards:

- Battery safety testing: IEC 62133:2012
- Transportation safety testing of lithium batteries: UN38.3:2009 T

Performance Data

A pre-clinical study was conducted comparing tissue oxygen hemoglobin saturation (S_tO_2) measurements taken with the predicate Kent Camera (KD203) and the modified device (KD204). The agreement study used a forearm ischemia protocol to evaluate the performance of the devices both within the expected normal range of S_tO_2 as well as situations where S_tO_2 is depressed. The forearm ischemia protocol was intended to test the devices over the clinically meaningful dynamic range of S_tO_2.

The study objectives were as follows:

- Demonstrate the new S_tO_2 algorithm has superior performance and stability when measuring low reflectivity tissue than the predicate algorithm.
- Demonstrate the linear relationship between the S_tO_2 measurements from the two devices over a clinically meaningful dynamic range of S_tO_2.
- Through the use of Bland-Altman plots quantify any scale shift (slope) and bias (difference in mean values) between the devices and estimate the 95% levels of agreement.

Field data acquired on 38 volunteer subjects undergoing a forearm ischemia – reperfusion challenge confirmed stimulation and lab bench testing that the replacement algorithm provides estimates for relative oxy- [Hbo] and deoxy- [Hb] hemoglobin linearly related to the original (predicate) algorithm $R^2 > 0.98$ with RMSE r[Hb] = 0.000239 and RMSE r[Hbo] = 0.00208. These hemoglobin estimates are used to calculate an estimated tissue hemoglobin oxygenation (S_tO_2). S_tO_2 = r[Hbo] / (r[Hb] + r[Hbo]). Linear regression in conjunction with Bland – Altman analysis was used to compare S_tO_2 estimates for the predicate algorithm and the proposed replacement algorithm.

The agreement study concluded that S_tO_2 measurements from the modified device (KD204) and the predicate Kent Camera (KD203) show a linear relationship over a wide and clinically meaningful dynamic range of S_tO_2. These findings support the use of the modified device (KD204) to non-invasively measure superficial tissue hemoglobin oxygen saturation.

Basis of Substantial Equivalence

The KD204 (K201976) near infrared imaging device has the same indications for use, similar technology characteristics and principles of operation as the predicate device, KD203 (K163070). The modifications between the KD204 and KD203 do not raise new or different types of questions regarding safety and effectiveness. Non-clinical performance data supports the safety and effectiveness of the KD204 device.

Therefore the KD204 (K201976) is considered substantially equivalence to the KD203 (K23432).