April 2, 2024

Kent Imaging Inc
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K240601
Trade/Device Name: SnapshotNIR model KD205
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: March 3, 2024
Received: March 4, 2024

Dear Dave Yungvirt:

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.

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

Tanisha L. Hithe -S
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Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K240601

Device Name

SnapshotNIR (KD205)

Indications for Use *(Describe)*

SnapshotNIR (KD205) is intended for use by healthcare professionals as a non-invasive tissue oxygenation measurement system that reports an approximate value of:
- oxygen saturation (St02),
- relative oxyhemogoblin level (Hb02), and
- relative deoxyhemoglobin (Hb) level

in superficial tissue. SnapshotNIR (KD205) displays two-dimensional color-coded images of tissue oxygenation of the scanned surface and reports multispectral tissue oxygenation measurements for selected tissue regions.

SnapshotNIR (KD205) 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
K240601

April 2, 2024

Device Name: SnapshotNIR (KD205)

Submittal Information:

Post-approval contact:
Hitalo Arume

Kent Imaging Inc.
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Calgary, AB CANADA T2R 1L3

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Device and Classification Name

	SnapshotNIR (KD205)
Classification Name	Oximeter, Tissue Saturation
Classified Under	21CFR 870.2700
Classification of Device	Class II
Classification Panel	Cardiovascular
Product Code	MUD

Predicate Device: SnapshotNIR (KD204)

Reference Device: Kent Camera (KD203)

Indications for Use

SnapshotNIR (KD205) is intended for use by healthcare professionals as a non-invasive tissue oxygenation measurement system that reports an approximate value of:

- oxygen saturation (St02),
- relative oxyhemogoblin level (Hb02), and
- relative deoxyhemoglobin (Hb) level

in superficial tissue. SnapshotNIR (KD205) displays two-dimensional color-coded images of tissue oxygenation of the scanned surface and reports multispectral tissue oxygenation measurements for selected tissue regions.

SnapshotNIR (KD205) is indicated for use to determine oxygenation levels in superficial tissues.

Device Description

SnapshotNIR (KD205) is a medical device that operates like a camera. The SnapshotNIR device is completely non-contact, capturing images from 12 inches away from the patient or other imaging field-of-views. The device uses six near-infrared wavelengths of light and white light emitting diodes (LEDs) to produce a resultant tissue oxygenation image and a colour-based "RGB" or clinical image, respectfully, that can be viewed on the touchscreen display.

SnapshotNIR is based on multispectral imaging technology and performs spectral analysis at each pixel to determine the approximate values of tissue oxygen saturation (StO2), oxyhemoglobin levels (HbO2), and deoxyhemoglobin levels (Hb) in superficial tissues and displays a two-dimensional, color-coded image of the tissue oxygen saturation (StO2).

SnapshotNIR consists of:
• SnapshotNIR
• Recharger
• User Guide
• Quick Start Guide
• Sterile Drape (Optional)

The intended use and user interaction remained the same in the new model (KD205). The user will notice that the modified device no longer requires the user to take a calibration image prior to image capture. SnapshotNIR now uses an embedded computer module and a touchscreen LCD. Additional minor form factor changes were made on the new model (KD205) to accommodate the hardware change. With respect to the software used by SnapshotNIR, the predicate and new model (KD205) operate similarly.

Fundamental Principles

The SnapshotNIR (KD205) has identical fundamental working principles to the predicate camera. SnapshotNIR builds on the standard principles used in other oximeters and tissue oxygenation measurement systems. Tissue oxygenation devices expose tissue with light of known wavelengths and capture reflected light that is not absorbed by the tissue. Wavelengths are chosen to provide spectral information about the hemoglobin oxygen content. Tissue oxygen saturation (StO2) is calculated as:

$$StO_2 = \frac{[HbO_2]}{[Hb]+[HbO_2]}$$

For viable (blood-perfused) tissue, hemoglobin is a dominant absorber of light within the near infrared (near-IR) region of the electromagnetic spectrum, specifically between 600nm to 1000nm. The well documented and established absorption spectra exhibited by oxygenated hemoglobin (HbO2) and deoxygenated hemoglobin (Hb) enables near-IR spectroscopy to determine the proportions of HbO2 and Hb within the tissue. SnapshotNIR visualizes the tissue oxygen saturation levels at each image pixel reflected from the superficial capillary bed of the tissue being imaged based on the reflectance characteristics of HbO2 and Hb.

Nonclinical data

Nonclinical engineering-based tests (e.g., IEC 60601-1, IEC 60601-1-2, etc) among other performance bench tests support conclusions that the KD205 device is safe for use with a low risk of adverse events occurring during the intended use scenarios. These tests and findings are analogous to those conducted on the predicate KD204 SnapshotNIR device and demonstrate that the KD205 device is similarly safe, and effective compared to a current legally marketed device.

Finally, the KD205 SnapshotNIR device has made improvements over the predicate KD204 device. In a sub-analysis of the pre-clinical dataset, the KD205 device demonstrated no significant differences (derived via 2-way ANOVA models) in STO2 across the ischemia-reperfusion test when comparing cohorts of low versus high tissue scattering effects. This outcome is considered an improvement comparative to the KD204 device whereby non-physiological measurements were derived from the high tissue scattering cohort due to suboptimal signal-to-noise ratios of near-infrared light which impairs the calculation of STO2.

Substantial Equivalence

The modified device (SnapshotNIR, model KD205) has the same regulatory information as the predicate device (Snapshot$_{NIR}$, model KD204) and the same regulatory information as the reference device (Kent Camera, model KD203).

Detailed Comparative Features between Devices.

Comparative Feature	SnapshotNIR - KD205	Predicate SnapshotNIR – KD204
Indications for Use	Same	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), oxyhemoglobin level (HbO2), and 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.
Measurements	Same	• Oxygen saturation • Oxyhemoglobin level • Deoxyhemoglobin level
Method of Measurement	Same	Non-invasive, non-patient contacting imaging head illuminates the surface and receives returned light.
	Same	6 wavelengths between 600nm and 1000nm.

Comparative Feature	SnapshotNIR - KD205	Predicate SnapshotNIR – KD204
	Same	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.
Light Source	Same	LEDs
Lens	Same	Corrected and optimized for use from 400nm to 1000nm.
Output Display	Same	• Two-dimensional color-coded map of estimated oxygen saturation • Numeric data
Power Source	Same	DC (battery-powered)
Patient Contact	Same	None
Control Method	Same	Computer controlled.
Calibration	Device is factory calibrated to account for range of operating conditions.	Preformed at start-up by operator and repeated if operating conditions of camera change to the degree that necessitates recalibration.
Sterility	Same	Device is not considered sterile.
Software Language	Same	C#
Selection Tools	Same	Circle Region/Perimeter Line
Region of Interest (ROI) Area	Same	Support freehand drawing ROI selection (cm^2).
User Interface	Embedded CPU, touchscreen LCD and battery incorporated into camera enclosure.	Off-the-shelf touchscreen PC incorporated in enclosure with camera and battery.
System Components	Camera and recharger.	Camera, calibration card and recharger.
Data storage	Same	Patient images are stored in a proprietary secure format on the device and patient information is stored in an encrypted database on the device. Patient images and database are hidden on device.

Comparative Feature	SnapshotNIR - KD205	Predicate SnapshotNIR – KD204
Connectivity and Reporting	Same	User can create reports and email through Wi-Fi connectivity.
	Software upgrades performed via USB or through cloud. Log files can also be uploaded to cloud for support.	Software upgrades performed via USB.
Expiration Date	Same	No expiration date.

Conclusion

The modified SnapshotNIR (KD205) is substantially equivalent to the predicate Snapshot$_{NIR}$ (KD204)