DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 05, 2017

Kent Imaging Inc.
Darrell Barnhart
Vice President
1440, 720 – 13th Avenue SW
Calgary, T2R 1M5 CA

Re: K163070
Trade/Device Name: Kent Camera
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: April 4, 2017
Received: April 5, 2017

Dear Darrell Barnhart:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163070

Device Name
Kent Camera

Indications for Use *(Describe)*
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),
- relative oxyhemoglobin level (HbO2), and
- relative 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.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Kent Camera (May 4, 2017)

Submittal Information:

Post-approval contact:
Darrell Barnhart
Kent Imaging Inc.
1440, 720 - 13th Avenue SW
Calgary, AB, Canada T2R 1M5

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

Device and Classification Name

Proprietary Name:	Kent Camera
Common Name:	Tissue Oximeter
Classification Name:	Oximeter, Tissue Saturation (21 CFR 870.2700, Product Code: 74 MUD)

Predicate Device
Kent Camera, 510(k) K113507, Kent Imaging Inc.

Intended 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 (S_tO_2),
- relative oxyhemoglobin level (HbO_2), and
- relative 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.

Device Description

The Kent Camera is a handheld digital camera 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. The Kent Camera determines the approximate values of oxygen saturation (S_tO_2), relative oxyhemoglobin (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 a camera, a recharger, and a reference card for calibration and is used by healthcare professionals in a healthcare environment to determine oxygenation levels in superficial tissues for a patient population with potential circulatory compromise.

Comparison to predicate device

Comparative Feature	Kent Imaging, Inc. Modified Kent Camera	Kent Imaging, Inc. Predicate Kent Camera	Significant Differences
Indications for Use	Same	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 (S_tO_2), relative oxyhemoglobin (HbO_2) 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.	none
Measurements	Same	• oxygen saturation • relative oxyhemoglobin level • relative deoxyhemoglobin level	none
Method of Measurement	Same	Non-invasive, non-patient contacting imaging head illuminates the surface and receives returned light	none
	Minor center wavelength change and increased bandwidth	Four wavelengths between 600nm and 1000nm	Different. Both use specific weighted coefficients. The change had no effect on performance and does not present any additional safety or effectiveness concerns.
	A CMOS image sensor with global shutter is used as the detector	A wavelength-filtered CMOS image sensor with rolling shutter is used as the detector	Similar. Both are CMOS sensors. The change in shutter type had no effect on performance and does not present any additional safety

			or effectiveness concerns.
	Same	Spectral analysis at specific wavelengths of light returned from the target tissue	none
Light Source	Higher intensity, shorter duration	Lower intensity, longer duration	Similar. Both use LEDs. The change in LEDs had no effect on performance and does not present any additional safety or effectiveness concerns.
Ambient Light	Insignificant contribution to image (relative to NIR LEDs) due to short exposure time	Blocked by optical filters	Different. Both compensate for ambient light. The change in filtering of light had no effect on performance and does not present any additional safety or effectiveness concerns.
Excessively Bright Ambient Light	Same	Checked for in software	none
Working Distance	Approximately 12”	Approximately 16”	Similar. Both have the same approximate working distance. The change in working distance had no effect on performance and does not present any additional safety or effectiveness concerns.
Output Display	Same	• Two-dimensional color-coded map of estimated oxygen saturation • Numeric data	none
Power Source	DC (battery-powered)	AC	Different. The device power source was changed from AC to DC (battery-powered). The change from AC to DC (battery-powered) does not affect the oxygenation data provided, had no effect on performance and does not present any additional safety or effectiveness concerns.
Patient Contact	Same	None	none

Patient Population and Environment	Same	Healthcare environment for patient population with potential circulatory compromise	none
Location of Measurement	Same	Two-dimensional area of superficial tissue	none
Control Method	Same	Computer controlled	none
Calibration	Same	Preformed at start-up by operator. Performed periodically during extended picture capturing sessions	none
Sterility	Same	Camera and components are not supplied sterile, nor are they considered sterile or are to be sterilized	none
User Interface	Same	• DC-powered touchscreen PC • DC-powered camera (imaging head)	none
	Computer and a battery incorporated into camera enclosure	Stand based design supporting computer, power supply and camera head	Different. The update of the camera from the stand-based device to a handheld device involved changes to the power source, overall dimensions and packaging. The change from stand-based to handheld had no effect on performance and does not present any additional safety or effectiveness concerns as the fundamental scientific, multispectral imaging, technology is the same.

Nonclinical Tests

To support the substantial equivalence, the modified Kent Camera, like the predicate device before, went through and passed both internal testing for user and design requirements as well as international standards. The Kent camera passed testing for the following standards:

- Electrical safety and essential performance: ANSI/AAMI ES60601-1
- Electromagnetic compatibility: IEC 60601-1-2

As mentioned previously, the modified Kent camera is battery (DC) powered. A medical grade battery was purchased for this purpose and it is compliant with the following standards:

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

The predicate device uses LEDs in combination with bandpass filters in front of the detector to illuminate the target within narrow passbands. The subject device uses LEDs with minor changes in center wavelength and no bandpass filters which increases the bandwidth of each wavelength. Appropriate matching extinction coefficients are employed and weighted in the subject device to reflect the minor wavelength changes and increased bandwidth of each LED emission profile. This results in both cameras having effectively the same performance in obtaining S_tO_2 values even in the presence of noise.

Performance Data

A pre-clinical study was conducted comparing tissue oxygen hemoglobin saturation (S_tO_2) measurements taken with the battery-powered Kent Camera (KC203) and the predicate Kent Camera (KC103). 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 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.

The volunteers for our agreement study self-reported as being healthy. We did no further screening to assess their vascular or general health. The study population consisted of 7 females and 10 males ranging in age from 23 to 72 with the mean age of the study participants being 49. The protocol involved taking pairs of S_tO_2 pictures with the two cameras of the same region of the volar forearm in quick succession. These were considered matched pairs. Matched pairs of pictures were collected with the forearm under normal baseline perfusion for each subject. Matched pairs of pictures were taken over 3 minutes with the blood flow to the forearm being occluded and for a further 3 minutes with perfusion restored (reperfusion). This occlusion – reperfusion cycle was repeated a second time for each study participant.

<u>Endpoints Demonstrating Agreement</u>

The devices show a linear agreement over a wide dynamic range of S_tO_2 spanning the range expected for normal healthy tissue and ischemic tissue. The Deming regression line of agreement has a 95% confidence interval for the slope [0.932 0.959] and intercept [0.020 0.040]. The Bland-Altman analysis shows little to no bias between the devices, 95% confidence interval for the intercept [-0.004 0.003] S_tO_2 units (using S_tO_2 reported on a scale of 0 to 1). The slope -0.0057, [-0.009 -0.002] indicates less than a 1% scale shift between the two cameras. The 95% limits of agreement (LoA) for the battery-powered minus the predicate device being -0.13 to 0.12 S_tO_2 units. More than 85% of the paired measurements from the two cameras differ less than 0.1

S_tO_2 units. The agreement study concluded that S_tO_2 measurements from the battery-powered Kent Camera (KC203) and the predicate Kent Camera (KC103) show a linear relationship over a wide and clinically meaningful dynamic range of S_tO_2. The devices share a common scale (within 1%) and show minimal to no bias. These findings support the use of the battery-powered Kent Camera (KC203) to non-invasively measure superficial tissue hemoglobin oxygen saturation.

Conclusion

The predicate camera received 510(k) clearance in August 2012. Both cameras work by emitting near-infrared (NIR) light from light emitting diode (LED) sources, illuminating an area of tissue and collecting the back-scattered NIR light from the illuminated area. Both devices use back-scattered light centred at 4 distinct near-infrared wavelengths well displaced from the isobestic point of hemoglobin (the point where oxygen bound hemoglobin and hemoglobin without bound oxygen have equal light absorbance). Using the publicly available, and widely validated, near-infrared optical properties of hemoglobin and measuring the back-reflected near-infrared light, both devices determine the relative proportion of oxygen bound hemoglobin to the total hemoglobin in the microvascular bed (tissue hemoglobin oxygen saturation, S_tO_2) using a modified Beer-Lambert model.

In order to determine the operational equivalence of the battery-powered camera and the predicate camera, a convenience sample of 17 volunteer participants were measured over the course of a forearm ischemia protocol. This protocol offers a simple, yet clinically safe method to temporarily change hemoglobin oxygen levels of the forearm. Matched measurements were made with both devices and parametric correlation analysis was used to determine the linear relationship between the battery-powered camera and the predicate camera. The study demonstrated that S_tO_2 values from both cameras show an excellent linear correlation, 95% CI for slope [0.932 0.959] and intercept [0.020 0.040], evaluated over wide range of S_tO_2 levels encompassing the clinical range expected for normal, mildly ischemic and critically ischemic conditions. Based on our study we can unequivocally state that both cameras report a drop from basal S_tO_2 levels under conditions of known ischemia and report a trend in S_tO_2 values consistent with the physiological response expected for forearm ischemia – reperfusion. The study supports the intended field of use for our camera, to help visualize local or regional tissue hemoglobin oxygenation (S_tO_2) in the general population. The two devices show an excellent linear relationship and provide S_tO_2 readings which statistically and operationally are not significantly different.

Basis of Substantial Equivalence

Based on identical manufacturer, intended use, unaltered fundamental scientific technology, equivalent effectiveness and safety results from comparative performance testing, the modified Kent Camera (KC203) is substantially equivalent to the unmodified Kent Camera (KC103).