Rfpi
% Jerzy Wojcik
Sr Director RA/QA
EdgeOne Medical
455 N Campbell Ave
Chicago, Illinois 60612

December 14, 2018

Re: K181269
Trade/Device Name: iCertainty
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II
Product Code: DPW
Dated: November 20, 2018
Received: November 26, 2018

Dear Jerzy Wojcik:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Neil R Ogden -S

Digitally signed by Neil R Ogden -S
Date: 2018.12.14 15:00:03 -05'00'

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*

K181269

Device Name
iCertainty

Indications for Use *(Describe)*

The iCertainty System is intended for non-invasive two-dimensional imaging as an adjunctive method for evaluation of blood flow distribution (flow and perfusion) in tissues, up to a depth of 4-5mm.

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.

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510(k) Summary

Date Summary Prepared:	December 12, 2018	
510(k) Owner:	RFPi	
Contact Person:	Jeffery Basham CEO, RFPi 1800 N Greene Street, Suite K Greenville, NC 27834 919-280-2953 Jeff.basham@rfpi-co.com	
	510(k) Consultant Contact: Jerzy Wojcik Sr. Director RA/QA, EdgeOne Medical 455 N Campbell Ave, Suite 2N Chicago, IL 60612 312-300-6643 Jerzy.wojcik@edgeonemedical.com	
Device Name:	Device Name:	iCertainty
	Trade Name:	iCertainty
	Common Name:	Flowmeter, Blood, Cardiovascular
	Regulation:	870.2100
	Class:	II
	Product Code:	DPW
Predicate Device(s):	Primary Predicate	K120884 PeriCam PSI
	Reference Device	K063345 Novadaq SPY
Device Description:	The iCertainty System is a device used to image blood flow distribution (flow in vessels and perfusion in tissues) in real time. The device employs a mobile cart so that it can be configured in the appropriate orientation to properly image the tissue in an operating room environment without restrictions. When a practitioner elects to use imaging as an adjunct to evaluate blood flow distribution, the device is moved into the appropriate	

position and an extension arm with an optical head unit (OHU, containing the lasers/camera equipment) is positioned over the patient as described in the instructions for use. The OHU is moved to a specified height (focused) over the target image area and the imaging is performed. The imaging can be performed as often as deemed necessary by the surgeon during the procedure to visualize blood flow distribution (blood flow in vessels and perfusion in tissues) in the target tissues being operated upon. The device employs a dual laser-based system with a camera imaging system. The two lasers (450nm and 785nm) illuminate the surface and blood flow distribution up to a depth of 4-5mm of the target tissue. A digital camera records the image in real time. All real-time blood flow distribution analyses are performed on a central computer within the device. Real-time images are displayed to the surgeon on an imaging display. Data entry is performed on a separate display and data entry keyboard. A sterile drape is used as an accessory to protect the sterile operating field from contamination during use.

Statement of Intended Use:	The iCertainty System is intended for non-invasive two-dimensional imaging as an adjunctive method for evaluation of blood flow distribution (flow and perfusion) in tissues, up to a depth of 4-5mm.
Accessory Device:	Premier Guard sterile drape (K041501)

Device Comparisons			
Feature	**iCertainty Proposed Device**	**Primary Predicate PeriCam PSI (K120884)**	**Reference Device Novadaq Spy (K063345)**
Intended Use / Indications	…for non-invasive two-dimensional imaging as an adjunctive method for evaluation of blood flow distribution (flow and perfusion) in tissues, up to a depth of 4-5mm.	…for non-invasive two-dimensional imaging of peripheral tissue blood perfusion.	… for capturing and viewing fluorescent images for the visual assessment of blood flow as an adjunctive method for the evaluation of tissue perfusion, and related tissue transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive surgical procedures.
	Conclusion – Both the subject and predicate devices have the same intended use as an adjunctive method for evaluation of blood flow and perfusion.		
Target Users	Surgeons, physicians, nurses and other trained medical professionals	Surgeons, physicians, nurses and other trained medical professionals	Surgeons, physicians, nurses and other trained medical professionals
	Conclusion – Substantially equivalent. All three devices have the same target users.		
Targeted anatomical sites	Targeted surgical tissues exposed to the device field of view, including both central organ and peripheral tissues	Targeted peripheral tissues exposed to the device field of view	Targeted surgical tissues exposed to the device field of view, including both central organ and peripheral tissues
	Conclusion – Substantially equivalent. All three devices image tissue that are in the field of view of the device, including central organ and peripheral tissues in the subject and primary predicate devices.		
Mechanism of Action / Technology	Laser light illuminates the target surface tissue. Using both optical reflectance and laser speckle contrast analysis, the pattern reflected from the blood in the tissue is processed and imaged to generate images of blood perfusion in target tissues up to a depth of 4-5 mm.	Laser light illuminates the target surface tissue. Using laser speckle contrast analysis, the pattern reflected from the blood in the tissue is processed and imaged to generate images of blood perfusion (depth not determined, should be similar to iCertainty by optical physics parameters).	Laser light illuminates the target surface tissue which has a fluorescent dye coursing through blood vessels introduced through an intravenous injection. The laser excites the dye, which emits an infrared light. The infrared pattern reflected is processed and imaged to generate images of blood perfusion (depth not determined).

<table>
<tr><th colspan="4">Device Comparisons</th></tr>
<tr><th>Feature</th><th>iCertainty Proposed Device</th><th>Primary Predicate PeriCam PSI (K120884)</th><th>Reference Device Novadaq Spy (K063345)</th></tr>
<tr><td></td><td colspan="3">Conclusion – Substantially equivalent to the predicate, PeriCam PSI and similar to the reference, Novadaq SPY. All three devices:
use laser light illumination of target tissues, then analyze the reflected light to generate images of blood perfusion;
have a laser illumination system, camera, computer software for analysis and display capabilities when in use;
have the capability to view, record and replay images of blood flow and perfusion in target tissues.
Differences between the subject and predicate and reference devices are:
the reference device requires an invasive injection of a fluorophobe ICG dye;
the subject and predicate device do not require an invasive injection;
the subject and predicate device use laser speckle contrast imaging analysis;
the reference device relatively quantifies the intensity of fluorescence as an indicator of flow and perfusion;
the subject device displays both the visible light and perfusion image side by side for user reference and orientation;
the predicates and reference present only the perfusion image.
The iCertainty technology used to achieve the intended use as compared to the predicate does not raise new questions of safety or effectiveness. Refer to Section 12.2 for further substantial equivalence discussion.</td></tr>
<tr><td rowspan="2">Method of Use</td><td>After preparing the device for use, the iCertainty is positioned above the targeted imaging site. The device is activated, and images are collected and viewed by the operator. If desired, the images can be viewed again at a later time.</td><td>After preparing the device for use, the PeriCam PSI is positioned above the targeted imaging site. The device is activated, and images are collected and viewed by the operator. If desired, the images can be viewed again at a later time.</td><td>After preparing the device for use, the patient is injected with a fluorescent dye. Novadaq SPY is positioned above the targeted imaging site. The dye must be delivered to the target tissue by the circulatory system. The device is activated, and images are collected and viewed by the operator. If desired, the images can be viewed again at a later time.</td></tr>
<tr><td colspan="3">Conclusion – Substantially equivalent. All three devices utilize the same method of use, in that the device is positioned over the target area and activated for collection of images for immediate viewing and/or again at a later time. Refer to Section 12.3 for further substantial equivalence discussion.</td></tr>
<tr><td rowspan="2">Electrical Safety and Electromagnetic Compatibility</td><td>IEC 60601-1 and 60601-1-2 compliant</td><td>IEC 60601-1 and 60601-1-2 compliant</td><td>IEC 60601-1 and 60601-1-2 compliant</td></tr>
<tr><td colspan="3">Conclusion – Substantially equivalent. All three devices are compliant with standards for electrical safety and compatibility.</td></tr>
<tr><td rowspan="2">Imaging Distance (Optical Head to Target Tissue)</td><td>32 +/- 3cm</td><td>30 cm</td><td>10 cm</td></tr>
<tr><td colspan="3">Conclusion – substantially equivalent. The subject device and SPY predicate device have comparable imaging distances.</td></tr>
<tr><td>Field of View</td><td>9 cm x 9 cm</td><td>Up to 24 cm x 24 cm</td><td>5 cm x 7 cm</td></tr>
</table>

Device Comparisons			
Feature	**iCertainty Proposed Device**	**Primary Predicate PeriCam PSI (K120884)**	**Reference Device Novadaq Spy (K063345)**
	Conclusion – The subject device and the predicate have comparable fields of view. The SPY reference device has a smaller field of view compared to the subject device. The larger FOV provides for a larger area of the target tissue to be captured in the imaging acquisition, from the same imaging distance.		
Depth of Penetration and detection	4-5 mm Documented Penetration 4-5 mm Documented Detection	Penetration and Detection not Reported	5-6 mm Reported Penetration (Detection not reported)
	Conclusion – similar to the reference device and not comparable to the Predicate. Only iCertainty has documented both depth of penetration and depth of detection.		
Resolution and Contrast	Image Resolution: 112µm/pixel Max: 1600 x 800 Data Points Resolution: 1600 x x800 pixels Speckle Contrast: 0-1	Image Resolution: 100µm/pixel Max: 1386 x 1038 Data Points Resolution: 1386 x 1038 pixels Speckle Contrast: 0-1	Image Resolution: not specified Max: 1024 x 768 Data Points Resolution: 1024 x 768 pixels
	Conclusion – Substantially equivalent. All three devices have the similar resolution and contrast.		
Image Presentation	Visible color and MSPV	Black and White NIR	Black and White NIR
	Conclusion – Substantially equivalent. All three devices display imaging that the user can interpret. However, the subject device has the added benefit of a visible light image of anatomic detail for user reference and orientation		
Imaging Depiction	Blood flow and perfusion	Blood flow and perfusion	Blood flow and perfusion
	Conclusion – Substantially equivalent. Imaging from all three devices depict blood flow and perfusion.		
User Interface	Keyboard, Graphical User Interface, Buttons on Camera head	Buttons on Camera head	Keyboard, Graphical User Interface, Buttons on Camera head
	Conclusion – Substantially equivalent. The reference device and iCertainty use a keyboard, graphical user interface and buttons on the camera head. Even though the predicate does not include a keyboard and Graphical User Interface, both components are required to be provided by the user in order to operate the predicate.		
Mode of Use	Mobile cart. When needed for imaging, the cart is positioned such that the arm can be extended into a position over the patient for imaging.	The device arm is mobile. When needed for imaging, the arm is mounted to a table or other surface such that the arm can be extended into a position over the patient for imaging.	Mobile cart. When needed for imaging, the cart is positioned such that the arm can be extended into a position over the patient for imaging.
	Conclusion – Substantially equivalent. All three devices are configurable to achieve orientation. The reference device and iCertainty are mobile carts that can be configured in the appropriate orientation with an extension arm that is positioned to image tissue without restrictions. The predicate is fixed to a surface but has an extension arm as well.		

Device Comparisons			
Feature	**iCertainty Proposed Device**	**Primary Predicate PeriCam PSI (K120884)**	**Reference Device Novadaq Spy (K063345)**
Setup	The iCertainty contains an adjustable arm which contains the laser and camera componentry and is mounted to a mobile cart which contained video screens, keyboard and computer.	The device has an adjustable arm which contains the laser and camera componentry and must be mounted to a table or mobile cart (not part of the device). The PeriCam PSI is then connected via firewall cable to a firewall port on a computer.	The device has an adjustable extension arm which contains the camera. The laser illumination system is mounted in the cart and connected to the Camera head by fiberoptic cable. The mobile cart also contains video screens, keyboard and computer.
	Conclusion – Substantially equivalent. All three devices have adjustable arms that are stabilized for use, and utilize a computer to operate the device. While the iCertainty and reference devices include a cart to which the arm is mounted and a computer to process imaging, the predicate requires the computer to be supplied by the user and the device to be mounted to a table or mobile cart. All three devices are substantially equivalent in that all require the same componentry in order to achieve their intended use.		
Imaging Cycles	10 imaging cycles, limited by software	Multiple imaging episodes per evaluation, limited by software	1 to 6 imaging cycles, limited by ICG Dye
	Conclusion – Substantially equivalent. Multiple imaging episodes can be obtained per case/evaluation.		
Size	81.3 x 81.3 x 198.1 cm 221 kg	PeriCam PSI Head: 22 x 15 x 20 cm PeriCam PSI Head 2.3/2.4 kg Arm and Stand 7.1/10.1 kg Total weight 9.4/12.5 kg (Standard/High resolution models)	81.2 x 81.2 x 180.4 cm 165 kg
	Conclusion – Substantially equivalent. The iCertainty and the reference devices are all-in-one devices which include the computer and stand/table/cart, whereas the predicate does not include the computer and stand/table/cart and this is smaller in size specification. All three devices have an imaging arm. The iCertainty and reference devices are of similar size, but the iCertainty device contains a larger counterweight, and thus weighs more. All three camera head units are of relatively similar size (but moderately different configurations).		
Maintenance / Cleaning	iCertainty is used with a sterile drape, which protects the patient from device contamination. Additionally, if cleaning or disinfection is required, the user manual provides instructions for cleaning.	The PeriCam PSI user manual provides instructions for cleaning.	The Novadaq SPY is used with a sterile drape, which protects the patient from device contamination. Additionally, if cleaning or disinfection is required, the user manual provides instructions for cleaning.

Device Comparisons			
Feature	**iCertainty Proposed Device**	**Primary Predicate PeriCam PSI (K120884)**	**Reference Device Novadaq Spy (K063345)**
	Conclusion – Substantially equivalent. Both the iCertainty and the reference device use a sterile drape to isolate the device arm and camera head from the sterile operative field, and both include the same instructions for cleaning or disinfection of non-sterile surfaces. The drapes do not alter the imaging characteristics. The predicate is not used in a true sterile environment, and thus does not require a drape. All three devices can be cleaned by the user/operator.		
Biocompatibility	The iCertainty does not come into contact with the patient. Materials of construction for the arm, camera head and cart, which are in contact with the user/operator for the purpose of movement and manipulation, are composed of plastic and metal commonly found in every-day materials. The device does not require the use on an injected fluorescent dye to achieve its intended use.	The PeriCam PSI does not come into contact with the patient. Materials of construction for the arm and camera head, which are in contact with the user/operator for the purpose of movement and manipulation, are composed of plastic and metal commonly found in every-day materials. The device does not require the use on an injected fluorescent dye to achieve its intended use.	The Novadaq SPY does not come into contact with the patient. Materials of construction for the arm, camera head and cart, which are in contact with the user/operator for the purpose of movement and manipulation, are composed of plastic and metal commonly found in every-day materials. The device requires the use of a biocompatible fluorescent dye (Indocyanine Green or ICG) which has a low toxicity profile.
	Conclusion – Substantially equivalent. All three devices are not in contact with the patient. User contact materials are considered safe common plastic and metal materials. The reference device requires use of a low-toxicity profile fluorescent dye to achieve intended use, while the iCertainty and predicate do not. The difference in the biocompatibility comparison with the reference device does not raise new questions of safety or effectiveness, and in fact reduces the safety risk for the iCertainty because the patient is not exposed to the fluorescent dye.		
Operating Conditions	Temperature: 10°C to 30°C Relative Humidity: 30-80% non-condensing Atmospheric Pressure Range: 700hPA to 1060hPA.	Temperature: 15°C to 30°C Relative Humidity: 10-80% non-condensing Atmospheric Pressure Range: 70 kPa to 160 kPa.	Temperature: 10°C to 30°C Relative Humidity: 10% to 90%, non-condensing Atmospheric Pressure Range: 94 kPa to 102 kPa
	Conclusion – Substantially equivalent. The operating conditions for all three devices are similar.		
Power Supply	Operates on standard Mains power supply in the United States.	Operates on standard Mains power supply in the United States.	Operates on standard Mains power supply in the United States.
	Conclusion – Substantially equivalent. All three devices operate using a standard Mains power supply in the United States.		

Performance Data: Performance testing was performed to verify that the performance of the iCertainty system is substantially equivalent to currently marketed perfusion flow imaging

systems, and substantially equivalent to the PeriCam PSI (K120884). Testing included:

- use testing
- data entry and integrity
- electrical safety
- electromagnetic compatibility
- sterile barrier/drape compatibility
- cleaning

In vivo blood flow and perfusion was evaluated through animal studies investigating skin/epidermis, static solid organ, vascular and moving solid organs in normal and diseased state.

Assessment of Clinical Data: Evaluation of human anatomy (hand, forearm and ankle from 40 patients) demonstrated that the iCertainty images blood flow distribution (flow and perfusion).

Overall Conclusions: Based on the indications for use, technological characteristics, and comparison to predicate devices, the iCertainty System has been shown to be substantially equivalent to the predicate.