December 4, 2019

MolecuLight Inc.
% Joel Ironstone
President
Ironstone Product Development
Suite 222, 276 Carlaw Avenue
Toronto, M4M 3L1 Canada

Re: K191371
Trade/Device Name: MolecuLight i:X
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: October 28, 2019
Received: October 29, 2019

Dear Joel Ironstone:

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)* K191371

Device Name

MolecuLight i:X

Indications for Use *(Describe)*

The MolecuLight i:X 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 MolecuLight i:X device should not be used to rule-out the presence of bacteria in a wound.

The MolecuLight i:X 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.

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K191371
510(k) SUMMARY

MolecuLight *i:X*

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

MolecuLight Inc.
Suite 700, 425 University Avenue
Toronto, ON, Canada
M5G 1T6
Phone: 647-362-4684
Contact Person: Tyler Chackowicz

Date Prepared: December 3, 2019

Name of Device

MolecuLight i:X

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

Predicate Devices

Fluobeam 800 Clinic Imaging Device (DEN170092, Predicate Device)
WoundVision Scout (Class I, Predicate Device)
MolecuLight i:X (DEN180008, Reference Device)

Indications for Use

The MolecuLight i:X 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 MolecuLight i:X device should not be used to rule-out the presence of bacteria in a wound.

The MolecuLight i:X does not diagnose or treat skin wounds.

Device Description

The MolecuLight i:X Imaging Device is a handheld medical imaging device comprised of a high-resolution color LCD display and touch-sensitive screen with integrated optical and microelectronic components. MolecuLight i:X uses its patented technology to enable real-time standard digital imaging and fluorescence imaging in wounds and surrounding healthy skin of patients as well as wound area measurements.

Clinical Testing

Clinical testing was performed to evaluate the potential increase in the identification of wounds containing >10^4 CFU per gram of bacteria when the MolecuLight i:X is added to a clinician's evaluation of a subject's clinical signs and symptoms (CSS). In the study, the clinician's interpretation of the MolecuLight i:X fluorescence image and CSS were compared to quantitative microbiological analysis.

The baseline demographics of the study population is provided in the Table 1 below.

Table 1 Baseline demographics of study population

Characteristic	**Measure**	**All patients (n = 350)**	**Microbiology Positive (n=287)**	**Microbiology Negative (n=63)**
Age (years)	Mean (SD) Median (Minimum, Maximum)	60.19 (12.44) 59.76 (27.83, 96.03)	59.95 (12.11) 59.72 (27.83, 94.76)	61.27 (13.87) 60.27 (28.47, 96.03)
Sex (Female)	Count (%)	125 (35.71)	87 (30.31)	38 (60.32)
Systemic Antibiotic Use (Yes)		90 (25.71)	56 (19.51)	34 (53.97)
Fitzpatrick Score Light (I or II) Medium (III or IV) Dark (V or VI)		 224 (64) 83 (23.71) 43 (12.29)	 179 (62.37) 74 (25.78) 34 (11.85)	 45 (71.43) 9 (14.29) 9 (14.29)

The clinical testing demonstrated that the fluorescence image, when used in combination with clinical signs and symptoms (CSS), increased the likelihood that clinicians could identify wounds containing bacterial loads >10^4 CFU per gram as compared to examination of CSS alone. The use of the MolecuLight i:X in combination with clinical signs and symptoms resulted in a <10% increase as compared to CSS alone in the rate in wounds that were incorrectly identified as having bacterial load >10^4 CFU/g, whose resulting bacterial load determined by conventional microbiological analysis was <10^4 CFU/g.

Measure	**Total (%) n= 350**	
	Sensitivity	Specificity
CSS+*iX*	60.98	84.13
CSS	15.33	93.65

No device attributable adverse events were recorded in the study. These study results demonstrated that the MolecuLight i:X increased the likelihood that clinicians can identify wounds containing wounds containing bacterial loads $>10^4$ CFU per gram as compared to examination of clinical signs and symptoms alone . The fluorescence output of the device is not ground truth regarding wound bacterial load $>10^4$ CFU/g and must be used in combination with CSS and other confirmatory methods such as bacterial culture, to make a determination of bacterial load.

Non-Clinical Testing

Nonclinical testing included the following on the subject device:

1) Standards Compliance Testing
2) Software Verification and Validation
3) System Verification and Validation
4) Cleaning and Disinfection Validation
5) Accuracy and Inter/Intra Reader Variability Testing of Wound Measurement Function
6) Bioburden Testing for the DarkDrape Accessory
7) Biocompatibility according to ISO 10993-1 including Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity for the DarkDrape and Wound Stickers.
8) Packaging and Transport validation

Compliance with Special Controls of 21 CFR 878.4550

The device complies with the all applicable special controls as per 21 CFR 878.4550 as follows:

1. A clinical study has been conducted that evaluates the device's performance under anticipated use conditions.
2. Patient Contact Materials have been demonstrated to be biocompatible.
3. Performance testing demonstrated the electromagnetic compatibility and electrical, mechanical and thermal safety of the device.
4. Software verification and validation has been completed.
5. LED light safety testing has been demonstrated according to IEC 60601-2-57:2011.
6. Labeling is provided that includes instructions for use as well as the performance of the device when used as intended.

Note: There are no components labeled as sterile included with this product.

Standards Compliance

MolecuLight i:X has been tested to comply with the following FDA recognized standards:

- Safety Testing per IEC 60601-1:2005+A1:2012& US National Differences per ANSI/AAMI ES 60601-1:2005/A1:2012
- EMC Testing per IEC 60601-1-2:2014 4th Edition

- LED Testing per IEC 60601-2-57:2011 and IEC 62471:2006
- Biocompatibility according to ISO 10993-1

Software Verification and Validation Testing

Software verification and validation testing was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

Comparison of Intended Use, Indications for Use and Technological Characteristics with the Predicate Device

The intended use for both the subject device, MolecuLight i:X, and predicate device, Fluobeam 800 Clinic Imaging Device (DEN170092), are the same. Both the subject and predicate devices illuminate target tissues or structures and detect a resulting autofluorescence image using a charge-coupled device (CCD) camera. Additionally, the subject device's wound measurement feature is similar in indication and technical characteristics to the second predicate device, WoundVision Scout. Table 2 below compares the characteristics of the subject device (MolecuLight i:X), the predicate device (Fluobeam 800 Clinic Imaging Device, DEN170092), and the reference device (MolecuLight i:X, DEN180008). Table 3 below compares the wound measurement characteristics of the subject device (MolecuLight i:X) and the predicate device (WoundVision Scout).

The subject device and the predicate devices have different technological characteristics. The submitted information, including both Non-Clinical and Clinical testing establish that the MolecuLight i:X device is at least as safe and effective as the predicate devices. Both devices operate on the principle of tissue autofluorescence, which is the property of fluorescent molecules (fluorophores) absorbing a wavelength of light and then emitting a longer wavelength of light. However, while the predicate device uses a laser for illumination, the subject device uses non-coherent light-emitting diodes (LEDs) as an excitation light source. These differences do not raise different questions of safety or effectiveness.

Table 2: Comparison of Technological Characteristics for Fluorescence Imaging

	SUBJECT DEVICE 'Modified' MolecuLight i:X	**PREDICATE DEVICE Fluobeam 800 Clinic Imaging Device (DEN170092)**	**REFERENCE DEVICE Granted MolecuLight i:X (DEN180008)**
Device Name	MolecuLight i:X	Fluobeam 800 Clinic Imaging Device	MolecuLight i:X
Manufacturer	MolecuLight Inc.	Fluoptics	MolecuLight Inc.
510(k) Number	-	DEN170092	DEN180008
Regulatory Class	Class II	Class II	Class I
Regulation Number	QJF	QDG	QCR
Product Classification	21 CFR 878.4550	21 CFR 878.4550	21 CFR 878.4165
Classification Name	Autofluorescence detection device for general surgery and dermatological use	Autofluorescence detection device for general surgery and dermatological use	Wound Autofluorescence Imaging Device

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.	A wound autofluorescence imaging device is a tool to view autofluorescence images from skin wounds that are exposed to an excitation light. The device is not intended to provide quantitative or diagnostic information.
Indications for Use	The MolecuLight i:X 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 MolecuLight i:X device should not be used to rule-out the presence of bacteria in a wound. The MolecuLight i:X does not diagnose or treat skin wounds.	The Fluoptics Fluobeam® Imaging system is intended to provide real-time near infrared (NIR) fluorescence imaging of tissue during surgical procedures. The Fluoptics Fluobeam® Imaging system is indicated for use in capturing and viewing fluorescent images for the visual assessment of blood flow in adults as an adjunctive method for the evaluation of tissue perfusion, perfused organs, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive and organ transplant surgeries. The Fluoptics Fluobeam® Imaging system can also be used to assist in the imaging of parathyroid glands and can be used as an adjunctive method to assist in the location of parathyroid glands due to the auto-fluorescence of this tissue. Use of the Fluobeam® device is intended to assist, not replace, experienced visual assessment, and biopsy with conventional histopathological confirmation per standard of care. The system is not to be used to confirm the absence of parathyroid tissue or glands and is only to be used to assist in locating visually identified gland/tissues.	The MolecuLight i:X 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, and (ii) view and digitally record images of fluorescence emitted from a wound when exposed to an excitation light. The MolecuLight i:X is for prescription use only.
Target Organ	Wounds	Tissue during surgical procedures	Wounds
Patient Population	Adult patients	Adult patients	Adult patients
Operating Modes	Standard and fluorescence imaging, video and image capture	Fluorescence imaging	Standard and fluorescent imaging, video and image capture
Excitation Light	405 nm light emitted from light emitting diodes (LED)s	750 nm emitted from a laser diode	405 nm light emitted from light emitting diodes (LED)s
Laser Power Density	N/A	5 ± 1 mW/cm^2	N/A
Infrared LED	N/A	Unknown	N/A
White LED	N/A	Broadband LEDs with normal illumination λ<800	N/A

Emission Wavelength	500-545 nm and 600-665 nm	>800 nm	500-545 nm and 600-665 nm
Contrast agent	Not required – autofluorescent target	Autofluorescent target or Indocyanine green (ICG)	Not required – autofluorescent target
Working Distance	8-12 cm	20-30 cm	8-12 cm
Resolution (focal plane)	5 megapixels	300 µm to 50 µm depending on magnification	5 megapixels
Magnification	N/A	X10 zoom	N/A
Maximum Frame Rate	30 images/sec	25 images/sec	30 images/sec
Camera Bit Depth	8 bits	8 bits	8 bits
Image Size (Pixels)	1136 x 640 pixels	696 x 576 pixels	1136 x 640 pixels
Image Format	JPEG	PNG	JPEG
Video Format	MOV	MP4	MOV
Software Operating System (OS) Compatibility	Apple iOS 9.3.5	Windows 7 or Windows 10	Apple iOS 9.3.5
Measurement Functionality	Wound length, width, and area measurements	None	None
Power Supply	Battery and Wall	Wall	Battery and Wall
Display	Handheld device; no remote display	Handheld device with remote display	Handheld device; no remote display
Patient Contacting Materials	Non-patient contacting device (held 8-12 cm from skin)	Non-patient contacting device	Non-patient contacting device (held 8-12 cm from skin)
Sterility	Used non-sterile	Used with off-the-shelf sterile sleeve when placed in the sterile field during surgical procedures	Used non-sterile
Electrical Safety	Compliance to IEC 60601-1	Compliance to IEC 60601-1	Compliance to IEC 60601-1
Mechanical Safety	Compliance to IEC 60601-1	Compliance to IEC 60601-1	Compliance to IEC 60601-1
Chemical Safety	No chemical delivered or used as part of the system	No chemical delivered or used as part of the system	No chemical delivered or used as part of the system
Standards with which the Device Complies	IEC 60601-1-2 IEC 60601-1 IEC 60601-2-57 IEC 62471	*As per K132475:* IEC 60601-1-2 IEC 60601-1 IEC 60825-1	IEC 60601-1-2 IEC 60601-1 IEC 60601-2-57 IEC 62471

Table 3: Comparison of Technological Characteristics for Wound Measurement

	SUBJECT DEVICE **'Modified' MolecuLight i:X**	**PREDICATE DEVICE – Wound Measurement** **WoundVision Scout**
Device Name	MolecuLight i:X	WoundVision Scout
Manufacturer	MolecuLight Inc.	Wound Vision LLC
510(k) Number	-	-
Regulatory Class	Class II	Class I
Regulation Number	QDG	FXN
Product Classification	21 CFR 878.4550	21 CFR 878.4160

Classification Name	Autofluorescence detection device for general surgery and dermatological use		TAPE, CAMERA, SURGICAL	
Intended Use / Indications for Use	The MolecuLight i:X 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 MolecuLight i:X device should not be used to rule-out the presence of bacteria in a wound. The MolecuLight i:X does not diagnose or treat skin wounds.		The Scout is a combination digital camera and long-wave infrared camera. The digital camera is indicated for the use of capturing visual images to measure the diameter, surface area, and perimeter of a part of the body or two body surfaces. The long-wave infrared camera is indicated for the use of capturing thermal images to measure the thermal intensity data of a part of the body or two body surfaces. Both components of the Scout are non-contact with respect to the patient and provide an adjunctive tool to help a trained and qualified health care professional measure and record external wound and body surface data. Intended for qualified healthcare professionals who are trained in its use, the Scout is a non-invasive and non-radiating device. The Scout is to be used on a patient population that includes non-pregnant female or male patients 18 years of age or older. The Scout is intended to be used in hospital, acute and sub-acute care settings, long term care, surgery, health care practitioner facilities, outpatient, home healthcare, or in any environment where health care is provided by a qualified health care professional. The Scout does not provide a diagnosis or therapy.	
Target Organ	Wounds		Body parts, including wounds	
Patient Population	Adult patients		Non-pregnant female or male patients 18 years of age or older	
Patient Contacting	Non-patient contacting		Non-patient contacting	
Operating Modes	Standard and fluorescence imaging and video		Standard and thermal imaging	
Imaging Aids	Non-sterile WoundStickers; DarkDrape		Unknown	
Measurement Functionality	Measures wound length, width, and area using standard imaging		Measures the diameter, surface area, and perimeter of a part of the body or the distance between two body surfaces using a standard image and measures the thermal intensity variation data of a part of the body or two body surfaces using a thermal image	
Measurement Results Part 1 (Wound Models)	Intra-rater	Length: 1.59 CV% Width: 1.92 CV% Area: 2.6 CV%	Intra-rater	Perimeter: 1.94 CV% Trace Area: 2.54 CV% LxW Area: 3.87 CV%
	Inter-rater	Length: 1.23 CV% Width: 1.28 CV% Area: 2.07 CV%	Inter-rater	Perimeter: 1.97 CV% Trace Area: 2.80 CV% LxW Area: 4.20 CV%
	Accuracy*	Length: 3.8% Width: 3.4% Area: 4.3%	Accuracy*	Perimeter: 2% Trace Area: 4%
Measurement Results Part 2 (Clinical Images)	Intra-rater	Length: 2.77 CV% Width: 3.11 CV% Area: 5.02 CV%	Intra-rater	Perimeter: 2.35 CV% Trace Area: 3.73 CV% LxW Area: 6.26 CV%
	Inter-rater	Length: 3.31 CV% Width: 5.42 CV% Area: 10.76 CV%	Inter-rater	Perimeter: 3.71 CV% Trace Area: 9.29 CV% LxW Area: 9.82 CV %
Record Functionality	Electronically stores captured images, videos and measurements		Electronically stores captured images and measurements	

In summary, MolecuLight i:X is substantially equivalent to the legally marketed predicate devices, Fluobeam 800 Clinic Imaging Device (DEN170092) and WoundVision Scout (for wound measurement). The intended use of the i:X device is the same as the Fluobeam, and the differences in technological characteristics do not raise different questions of safety or efficacy. In addition, the technical characteristics of the Modified MolecuLight i:X are identical to the reference device. Clinical testing and bench testing to FDA-recognized standards have demonstrated the safety and effectiveness of MolecuLight i:X with regards to differences in technological characteristics. Thus, the MolecuLight i:X is substantially equivalent to the Fluobeam and WoundVision Scout (for wound measurement).

Conclusion

MolecuLight i:X is substantially equivalent to Fluobeam and WoundVision Scout (for wound measurement).