May 18, 2022

MolecuLight, Inc.
Jordan John
Director, Quality Assurance & Regulatory Affairs
Suite 700, 425 University Avenue
Toronto, Ontario M5G 1T6
Canada

Re: K213840
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: QDG, QJF
Dated: April 13, 2022
Received: April 20, 2022

Dear Jordan John:

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 and Part 809); 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, D.Eng.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213840

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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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: Jordan John

Date Prepared: May 13, 2022

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

MolecuLight i:X (K210882)

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 (FL) imaging in wounds and surrounding healthy skin of patients as well as wound area measurements.

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

I. The intended use and technological characteristics of the subject MolecuLight i:X are identical to the previously cleared MolecuLight i:X. The only difference between the subject and predicate device are additional statements in the device's labeling clarifying: i) that the fluorescence in a region of a wound corresponds to the presence of elevated bacterial loads (>10^4 CFU/g); ii) that fluorescence in a region of a wound corresponds to the presence of more bacterial species and bacterial species of interest; iii) that species that produce red fluorescence is detectable by the MolecuLight *i*:X *in vitro*; iv) that Gram(+), Gram(-), aerobic and anaerobic species produce fluorescence detected by the MolecuLight i:X.

These statements do not change the indications for use of the device, and does not raise any new questions of safety or efficacy. The statement is supported by additional analysis of the clinical study reported in support of K191371.

Table 1: Comparison of Technological Characteristics for Fluorescence Imaging

	SUBJECT DEVICE MolecuLight i:X	**Predicate Device MolecuLight i:X (K210882)**
Device Name	MolecuLight i:X	MolecuLight i:X
Manufacturer	MolecuLight Inc.	MolecuLight Inc.
510(k) Number	-	K191371
Regulatory Class	Class II	Class II
Regulation Number	QJF	QJF
Product Classification	21 CFR 878.4550	21 CFR 878.4550
Classification Name	Autofluorescence detection device for general surgery and dermatological use	Autofluorescence detection device for general surgery and dermatological use
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.
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,	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,

	SUBJECT DEVICE **MolecuLight i:X**	**Predicate Device** **MolecuLight i:X (K210882)**
	(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.	(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.
Labelled relationship between Cyan fluorescence and *Pseudomonas aeruginosa*	Yes	Yes
Labelled relationship between region of a wound and presence of elevated bacterial loads ($>10^4$ CFU/g)	Yes	No
Labelled relationship between fluorescence in a region of a wound and the presence of more bacterial species and bacterial species of interest	Yes	No
Labelled relationship between species that produce red fluorescence and red fluorescence signature	Yes	No
Labelled relationship between fluorescence imaging and identifying wounds with elevated bacterial load including Gram	Yes	No

	SUBJECT DEVICE MolecuLight i:X	Predicate Device MolecuLight i:X (K210882)
(+) Gram (-), aerobic and anaerobic species.		
Target Organ	Wounds	Wounds
Patient Population	Adult patients	Adult patients
Operating Modes	Standard and fluorescence imaging, video and image capture	Standard and fluorescence imaging, video and image capture
Excitation Light	405 nm light emitted from light emitting diodes (LED)s	405 nm light emitted from light emitting diodes (LED)s
Laser Power Density	N/A	N/A
Infrared LED	N/A	N/A
White LED	N/A	N/A
Emission Wavelength	500-545 nm and 600-665 nm	500-545 nm and 600-665 nm
Contrast agent	Not required – autofluorescent target	Not required – autofluorescent target
Working Distance	8-12 cm	8-12 cm
Resolution (focal plane)	5 megapixels	5 megapixels
Magnification	N/A	N/A
Maximum Frame Rate	30 images/sec	30 images/sec
Camera Bit Depth	8 bits	8 bits
Image Size (Pixels)	1136 x 640 pixels	1136 x 640 pixels
Image Format	JPEG	JPEG
Video Format	MOV	MOV
Software Operating System (OS) Compatibility	Apple iOS 9.3.5	Apple iOS 9.3.5
Measurement Functionality	Wound length, width, and area measurements	Wound length, width, and area measurements
Power Supply	Battery and Wall	Battery and Wall
Display	Handheld device; no remote display	Handheld device; no remote display
Shelf-Life	2 Years	2 Years
Lifetime	5 Years	5 Years
Patient Contacting Materials	Non-patient contacting device (held 8-12 cm from skin)	Non-patient contacting device (held 8-12 cm from skin)
Sterility	Used non-sterile	Used non-sterile
Electrical Safety	Compliance to IEC 60601-1	Compliance to IEC 60601-1
Mechanical Safety	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
Standards with which the Device Complies	IEC 60601-1-2 IEC 60601-1 IEC 60601-2-57 IEC 62471	IEC 60601-1-2 IEC 60601-1 IEC 60601-2-57 IEC 62471

In summary, the modified MolecuLight i:X with the additional labeling statements is substantially equivalent to the legally marketed MolecuLight i:X. The intended use of the i:X device is the same as the predicate, and there are no differences in technological characteristics. The additional labeling statements do not raise different questions of safety or efficacy. Retrospective analysis has demonstrated the safety and effectiveness of MolecuLight i:X with regards to the additional labeling statements. Thus, the MolecuLight i:X is substantially equivalent to the previously cleared MolecuLight i:X.

Non-Clinical Testing

Each species listed produced red fluorescence that was detectable through fluorescence imaging with the MolecuLight i:X. To demonstrate this, all species were sub-cultured from frozen isolates and plated on commercially available Porphyrin Test Agar (PTA). Porphyrins fluoresce red under violet light illumination. Aerobic bacterial species were cultured and imaged at 24 and 40 hours, while slower growing anaerobic bacterial species were cultured and imaged at 40 and 120 hours. Negative controls were included and imaged at all time points. The fluorescence images taken with the MolecuLight i:X of each bacterial species were analyzed to determine the presence or absence of red fluorescence using a custom algorithm.

Clinical Performance Testing

Data from post hoc retrospective analysis of 78 patients were analyzed to evaluate the effectiveness of MolecuLight i:X to guide wound sampling to detect bacterial burden, including pathogens of interest, as defined by the CDC, compared to the Standard of Care (SoC) method of sampling, which is collected from the center of the wound.

Data from all wounds that had two samples obtained in the study were analyzed (N = 78). Samples targeted to the brightest location of fluorescence (FL-guided) were more likely to contain elevated bacterial load ($\geq 10^4$ CFU/g) compared to SoC-guided sampling at the center of the wound (See Table 2).

Table 2: Sensitivity of Soc-Guided Biopsy and FL-Guided Biopsy to Detect Any Species at Levels $\geq 10^4$ CFU/G in Patients with Two Biopsies Obtained

	SoC-guided sample	**FL-guided sample**	**P-value**
Sensitivity	87.2% (95% CI: 77.7%, 93.7%)	98.7% (95% CI: 93.06%, 99.97%)	P = 0.012

Fluorescence-guided biopsies detected a higher number of species compared to SoC-guided biopsies as described in Table 3.

Table 3: Count of Bacterial Species Detected by SoC and FL-guided Biopsies

	Number of Species by FL-guided Biopsy (N=78)	**Number of Species by SoC-guided Biopsy (N=78)**	**Difference in Number of Pathogens (FL Biopsy # - SoC Biopsy #)**	**P-value (paired t-test)**	**95% Confidence Interval**
Mean (SD)	3.026 (1.667)	2.231 (1.528)	0.795 (1.804)	P<0.001	0.388, 1.202
Med (Min, Max)	3.0 (0.0, 8.0)	2.0 (0.0, 6.0)			

FL-guided biopsies detected a higher number of pathogens of interest, defined by the CDC as increasing risk to develop antibiotic resistance, compared to SoC-guided biopsies as described in Table 4.

Table 4: Count of pathogens of interest detected by SoC and FL-guided biopsies

	Number of Pathogens of Interest by FL-guided Biopsy (N=78)	**Number of Pathogens of Interest by SoC-guided Biopsy (N=78)**	**Difference in Number of Pathogens of Interest** (FL Biopsy # - SoC Biopsy #)	**P-value (paired t-test)**	**95% Confidence Interval**
Mean (SD)	1.731 (1.124)	1.423 (1.134)	0.308 (0.916)	P=0.002	0.101, 0.514
Med (Min, Max)	2.0 (0.0, 5.0)	1.0 (1.0, 5.0)			

Conclusion

The modified MolecuLight i:X is substantially equivalent to the cleared MolecuLight i:X.