June 22, 2021

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

Re: K210882
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: March 24, 2021
Received: March 25, 2021

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); 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
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)*

K210882

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 grams 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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K210882

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: June 22, 2021

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 (K191371)

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.

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

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 is an additional statement in the device's labeling clarifying the relationship between the presence of a cyan fluorescence signature and the increased likelihood that wound contains *Pseudomonas aeruginosa*. This statement does 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 (K191371)**
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, (ii) Measure and digitally record the size of a wound, and	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.	(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	No
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
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 statement 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 statement does 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 statement. Thus, the MolecuLight i:X is substantially equivalent to the previously cleared MolecuLight i:X.

Non-Clinical Testing

No non-clinical performance testing was performed for this 510(k) submission.

Clinical Performance Testing

Data from 350 patients were retrospectively analyzed to evaluate the effectiveness of MolecuLight i:X to identify wounds with *Pseudomonas aeruginosa* at bacterial loads ≥ 10^4 CFU/g based on sensitivity, specificity, PPV, NPV, and likelihood ratio.

Table 2: Cyan Fluorescence in the Detection of Pseudomonas aeruginosa at Species Specific Levels ≥ 10^4 CFU/g

Fluorescence Signature	Sensitivity (95% CI)[a] n=32	Specificity (95% CI)[a] n=318	PPV[b] (95% CI)[a] n=30	NPV[b] (95% CI)[a] n=320	Likelihood Ratio (95% CI) N=30
Cyan	43.75% (26.26, 62.34)	94.97% (91.96, 97.10)	46.67% (28.34, 65.67)	94.38% (91.26, 96.63)	8.70 (4.69, 16.14)

- [a]Two-sided 95% Clopper Pearson Confidence Intervals.
- [b]The PPV and NPV are computed for the study prevalence of 9.14%.
- Likelihood ratio is the probability of a wound with *Pseudomonas aeruginosa* at Species Specific Levels ≥ 10^4 CFU/g being positive for cyan fluorescence divided by the probability of a wound that does not have *Pseudomonas aeruginosa* at Species Specific Levels ≥ 10^4 CFU/g being positive for cyan fluorescence.

Detailed retrospective analysis included assessment for the presence of any i:X fluorescence signature (red and/or cyan), presence of cyan fluorescence, presence of red fluorescence, and total bacterial load (TBL; CFU/g; sum of all species). Results for three separate analyses of the diagnostic parameters are presented below:

i. Fluorescence in the Detection of *Pseudomonas aeruginosa* at Species Specific Levels ≥ 10^4 CFU/g
ii. Fluorescence in the Detection of Total Bacterial Load (TBL) at Levels ≥ 10^4 CFU/g
iii. Fluorescence in the Detection Total Bacterial Load (TBL) at Levels ≥ 10^4 CFU/g in Absence of *Pseudomonas aeruginosa*

Table 3: Cyan, Red, and Cyan or Red Fluorescence in the Detection of *Pseudomonas aeruginosa* at Species Specific Levels ≥ 10^4 CFU/g

Test Output	Pa.High	Pa.Low	Post.Test.Risk (PPV)			Likelihood Ratio
			Post.Test.Risk	Lower Confidence Limit	Upper Confidence Limit	
Cyan FL	14	16	0.467	0.283	0.657	8.695
Red FL	14	145	0.088	0.049	0.143	0.959
Red or Cyan FL	25	150	0.143	0.095	0.204	1.656
Total	32	318	0.091	0.063	0.127	1.000

Table 4: Cyan, Red, and Cyan or Red Fluorescence in the Detection of Total Bacterial Load (TBL) at Levels ≥ 10^4 CFU/g

Test Output	TBL.High	TBL.Low	Post.Test.Risk (PPV)			Likelihood Ratio
			Post.Test.Risk	Lower Confidence Limit	Upper Confidence Limit	
Cyan FL	29	1	0.967	0.828	0.999	6.366
Red FL	152	7	0.956	0.911	0.982	4.767
Red or Cyan FL	168	7	0.960	0.919	0.984	5.268
Total	287	63	0.820	0.776	0.859	1.000

Table 5: Cyan, Red, and Cyan or Red Fluorescence in the Detection of Wounds with Total Bacterial Load (TBL) at Levels ≥ 10^4 CFU/g negative for *Pseudomonas aeruginosa*

Test Output	TBL (Absent PA).High	TBL (Absent PA).Low	Post.Test.Risk (PPV)			Likelihood Ratio
			Post.Test.Risk	Lower Confidence Limit	Upper Confidence Limit	
Cyan FL	15	1	0.938	0.698	0.998	3.706
Red FL	138	7	0.952	0.903	0.980	4.871
Red or Cyan FL	143	7	0.953	0.906	0.981	5.047
Total	255	63	0.802	0.754	0.844	1.000

Conclusion

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