July 21, 2021

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

Re: K211901
Trade/Device Name: MolecuLightDX
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: June 21, 2021
Received: June 21, 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)*
K211901

Device Name

MolecuLightDX

Indications for Use *(Describe)*

The MolecuLightDX 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 >104 CFU per gram as compared to examination of clinical signs and symptoms alone. The MolecuLightDX device should not be used to rule-out the presence of bacteria in a wound.

The MolecuLightDX 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

MolecuLightDX

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

MolecuLight Inc.
Suite 700, 425 University Avenue
Toronto, ON, Canada
M5G 1T6
Phone: 416-542-5522
Contact Person: Jordan John

Date Prepared: July 19, 2021

Name of Device

MolecuLight**DX**

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**DX** 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**DX** device should not be used to rule-out the presence of bacteria in a wound.

The MolecuLight**DX** does not diagnose or treat skin wounds.

Device Description

The MolecuLight**DX** Imaging Device is a handheld medical imaging device comprised of a high-resolution color AMOLED display and touch-sensitive screen with integrated optical and microelectronic components. MolecuLight**DX** 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.

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) Accuracy and Inter/Intra Reader Variability Testing of Wound Measurement Function
5) Packaging and Transport validation

Compliance with Special Controls of 21 CFR 878.4550

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

1. Patient Contact Materials have been assessed to be biocompatible.
2. Performance testing demonstrated the electromagnetic compatibility and electrical, mechanical and thermal safety of the device.
3. Software verification and validation has been completed.
4. LED light safety testing has been demonstrated according to IEC 60601-2-57:2011.
5. 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**DX** 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

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

Table 1: Comparison of Technological Characteristics for Fluorescence Imaging

	MolecuLightDX SUBJECT DEVICE	**MolecuLight *i:X* PREDICATE DEVICE**
Device Name	MolecuLight**DX**	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**DX** 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**DX** device should not be used to rule-out the presence of bacteria in a wound. The MolecuLight**DX** does not diagnose or treat skin wounds.	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.
Target Organ	Wounds	Wounds

	MolecuLightDX SUBJECT DEVICE	**MolecuLight *i:X* PREDICATE DEVICE**
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	405nm light emitted from light emitting diodes (LEDs)	405nm light emitted from light emitting diodes (LEDs)
Laser Power Density	N/A	N/A
Infrared LED	N/A	N/A
White LED	N/A	N/A
Emission Wavelength	500-545nm and 600-665nm	500-545nm and 600-665nm
Contrast Agent	Not required – autofluorescent target	Not required – autofluorescent target
Infrared Laser Distance Finder Wavelength	940nm	850nm
Infrared Laser Distance Finder Peak Power Output	17mW	14mW
Working Distance	8 – 12 cm (Fluorescence and Standard Imaging) 8 – 20 cm (Measurement Mode)	8-12cm (All imaging modes)
Torch	Yes	No
Optical head	3 Camera System	1 Camera
Resolution (focal plane)	8 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)	3264 x 2448 pixels	1135 x 640 pixels
Image Format	JPEG	JPEG
Video Format	MOV	MOV
Software Operating System (OS) Compatibility	Android 9.1	Apple iOS 9.3.5
Measurement Functionality	Stickerless Wound Measurement: Wound length, width, and area measurements	Wound length, width, and area measurements
Shelf-Life	2 Years	2 Years
Power Supply	Battery and wall	Battery and wall
Display	5.5” AMOLED	4” LCD

	MolecuLightDX SUBJECT DEVICE	**MolecuLight *i:X* PREDICATE DEVICE**
Patient Contacting Materials	Non-patient contacting device (held 8-20cm from skin)	Non-patient contacting device (held 8-12cm 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 IEC 60601-1-2 IEC 60601-2-57 IEC 62471	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57 IEC 62471

Conclusion

The performance tsting conducted on the MolecuLight**DX** demonstrates that the device can be used safely and effectively for the indications for use stated above. The MolecuLight**DX's** technological characteristics are similar to the technological characteristics of the predicate device (K191371) and does not raise new types of questions regarding safety and technology. The proposed MolecuLight**DX** is considered to be substantially equivalent to the MolecuLight ***i****:X* predicate device (K191371).