MolecuLight Inc.
% Jeffrey Shapiro
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street NW., Suite 1200
Washington, District of Columbia 20005

July 31, 2018

Re: DEN180008
Trade/Device Name: MolecuLight i:X
Regulation Number: 21 CFR 878.4165
Regulation Name: Wound autofluorescence imaging device
Regulatory Class: Class I
Product Code: QCR
Dated: February 16, 2018
Received: February 16, 2018

Dear Jeffrey Shapiro:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the MolecuLight i:X, a prescription device under 21 CFR Part 801.109 with the following 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, 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.

FDA concludes that this device should be classified into Class I. This order, therefore, classifies the MolecuLight i:X, and substantially equivalent devices of this generic type, into Class I under the generic name wound autofluorescence imaging device.

FDA identifies this generic type of device as:

> **Wound autofluorescence imaging device**. 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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE)

determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On February 16, 2018, FDA received your De Novo requesting classification of the MolecuLight i:X. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the MolecuLight i:X into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the MolecuLight i:X can be classified in class I. FDA believes that class I (general) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks to health are electrical/mechanical/thermal, electromagnetic compatibility (EMC) and optical safety of the device, and the error in fluorescence detection from the wound.

The wound autofluorescence imaging device is subject to the general controls of the FD&C Act. Section 510(l) of the FD&C Act (21 U.S.C. 360(l)) provides that a class I device is not subject to the premarket notification requirements under section 510(k) of the FD&C Act unless the device is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury. FDA has determined that the device does not meet these criteria and, therefore, premarket notification is not required for the device. Thus, persons who intend to market this device need not submit a premarket notification containing information on the wound autofluorescence imaging device they intend to market prior to marketing the device, subject to the limitations on exemptions in 21 CFR 878.9.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug

Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

If you have any questions concerning the contents of the letter, please contact Yasaman Ardeshirpour at 240-402-3706.

Sincerely,

Sergio M. De Del Castillo -S

Digitally signed by Sergio M. De Del Castillo -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300099523, cn=Sergio M. De Del Castillo -S
Date: 2018.07.31 10:54:43 -04'00'

Angela C. Krueger
Deputy Director, Engineering and Science Review
Office of Device Evaluation
Center for Devices and Radiological Health