December 5, 2023

Precision Healing LLC
% Christine Brauer
Regulatory Affairs Consultant
Brauer Device Consultants, LLC
7 Trail House Court
Rockville, MD 20850

Re: K230734
Trade/Device Name: Multispectral Imager Kit (MSI Kit) (300-00015), Multispectral Imager (MSI) (300-00009)
Regulation Number: 21 CFR 878.4165
Regulation Name: Wound Autofluorescence Imaging Device
Regulatory Class: Class I
Product Code: QCR, FXN
Dated: November 3, 2023
Received: November 6, 2023

Dear Christine Brauer:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tanisha L. Hithe -S
Tanisha L. Hithe -S
2023.12.05
11:33:57 -05'00'

Tanisha Hithe
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.

Submission Number *(if known)*

K230734

Device Name

Multispectral Imager Kit (MSI Kit) (300-00015);
Multispectral Imager (MSI) (300-00009)

Indications for Use *(Describe)*

The MSI is a handheld imaging tool that allows clinicians diagnosing and treating skin wounds to:
• View and digitally record images of a wound.
• Measure and digitally record the size of a wound.
• View and digitally record images of fluorescence emitted from a wound when exposed to an excitation light.
• View and digitally record thermal images of a wound.

The MSI 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

Applicant Information

Applicant/ 510(k) Owner: Precision Healing, Inc.
1200 Summit Avenue, Suite 414
Fort Worth, Texas 76102

Contact: Robert Brik, Director of Product Engineering
Precision Healing, LLC
1200 Summit Ave, Suite 414
Fort Worth, TX 76102
Telephone: 804.370.0291
Email: rbrik@dxwound.com

Date of Preparation: 30 November 2023

510(k) Number: K230734

Device and Classification Information

Trade Name:	Multispectral Imager Kit (MSI Kit) (PN 300-00015) Multispectral Imager (MSI) (PN 300-00009)
Common Name:	Autofluorescence imager Thermal imager
Classification Regulation:	21 CFR 878.4165 – Wound Autofluorescence Imaging Device 21 CFR 878.4160 – Surgical Camera and Accessories
Product Code:	QCR – Wound Autofluorescence Imaging Device FXN – Tape, Camera, Surgical
Class:	I I
Panel:	General and Plastic Surgery

Device Description

The MSI Kit includes the following: the MSI, a Universal Serial Bus (USB-C) cable, a wall adapter, and a carrying case.

The MSI captures and processes optical data of an imaged wound. The MSI consists of three imaging modalities: white light, autofluorescence and thermal. The MSI has 395nm excitation LEDs for autofluorescence imaging, a sensor for measuring distance to the wound, and a thermal sensor for capturing temperature gradients.

The MSI is powered by an onboard rechargeable battery and has a USB-C connection for uploading images to a computer. The manual provides users of the MSI with detailed instructions for proper use, maintenance, and storage.

Indication for Use

The indication for use is shown below.

> *The MSI is a handheld imaging tool that allows clinicians diagnosing and treating skin wounds to:*
>
> - *View and digitally record images of a wound.*
> - *Measure and digitally record the size of a wound.*
> - *View and digitally record images of fluorescence emitted from a wound when exposed to an excitation light.*
> - *View and digitally record thermal images of a wound.*
>
> *The MSI does not diagnose or treat skin wounds.*

Predicate Device Identification for Substantial Equivalence Comparison

For purposes of demonstrating substantial equivalence, the following predicate devices were selected:

- MolecuLight i:X by MolecuLight, Inc. authorized via DEN180008
- WoundVision Scout ("WoundVision") by WoundVision LLC cleared via K131596

Two predicate devices were selected in accordance with the guidance document entitled "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] - Guidance for Industry and Food and Drug Administration Staff" document issued on July 28, 2014. The MSI combines the intended use and imaging capabilities of each predicate device into a single device for user convenience without altering the fundamental intended use or risk profile of either device.

To the best of the applicant's knowledge, both predicate devices have been authorized for marketing, are legally marketed and have not been subject to a design-related recall.

Comparison of the Indication for Use and Intended Use between MSI and the Predicate Devices

The MSI Kit has the same intended use as each predicate device although there are slight differences in the indication for use statement. The MSI Kit and MolecuLight i:X share the same intended use – both devices are intended for use as an adjunctive tool that provides fluorescence and white light images for evaluation by a healthcare professional. Both devices are not intended to provide a diagnosis, but rather the healthcare professional remains responsible for the diagnosis and evaluation of the wound using the device as a tool (see Table 1). Both devices have the same purpose, function, target patient population, users and use environment, demonstrating they have the same intended use.

Both the MSI Kit and WoundVision Scout share the same intended use – both devices provide thermal images of a wound for use by healthcare professionals as an adjunctive tool. Both devices provide wound area measurements. Both devices share the same purpose, function, target patient population, users and use environment, demonstrating that they have the same intended use (see Table 2).

Table 1. Comparison of the Intended Use of the MSI Kit to the MolecuLight Predicate

Characteristic	**MSI Kit** **Precision Healing LLC**	**MolecuLight i:X** **MolecuLight Inc.** **DEN180008**
Regulatory Class:	Class I	Class I
Regulatory Number:	878.4165	878.4165
Regulation Name:	Autofluorescence detection device for general surgery and dermatological use	Autofluorescence detection device for general surgery and dermatological use
Product Code:	QCR – Wound Autofluorescence Imaging Device	QCR – Wound Autofluorescence Imaging Device
Indications for Use:	*... is a handheld imaging tool that allows clinicians diagnosing and treating skin wounds to:* • *View and digitally record images of a wound.* • *View and digitally record images of fluorescence emitted from a wound when exposed to an excitation light….* *The MSI does not diagnose or treat skin wounds.*	*... is a handheld imaging tool that allows clinicians diagnosing and treating skin wounds at point of care, to* *(i) View and digitally record images of a wound,* *(ii) View and digitally record images of fluorescence emitted from a wound when exposed to an excitation light.*
Purpose:	An adjunctive tool that provides white light images and fluorescence images of a wound for	An adjunctive tool that provides white light images and fluorescence images of a wound for

Characteristic	MSI Kit Precision Healing LLC	MolecuLight i:X MolecuLight Inc. DEN180008
	evaluation by a healthcare professional	evaluation by a healthcare professional
Function:	Outputs: • White Light Image • Red Fluorescence • Green Fluorescence • Blue Fluorescence	Outputs: • White Light Image • Red Fluorescence • Green Fluorescence
Target Population:	Adult patients with wounds	Adult patients with wounds
Prescription Device:	Yes	Yes
Target Users:	Healthcare professionals who care for and treat patients with wounds	Healthcare professionals who care for and treat patients with wounds
Use Environment:	Point-of-care with patient (e.g., office or clinic)	Point-of-care with patient (e.g., office or clinic)

Table 2. Comparison of the Intended Use of the MSI Kit to the WoundVision Scout Predicate

Characteristic	MSI Kit Precision Healing LLC	WoundVision Scout WoundVision LLC K131596
Regulatory Class:	Class I	Class I
Regulatory Number:	878.4160	878.4160
Regulation Name:	Surgical Camera and Accessories	Surgical Camera and Accessories
Product Code:	FXN – Tape, Camera, Surgical	FXN – Tape, Camera, Surgical
Indications for Use:	• *Measure and digitally record the size of a wound….* • *View and digitally record thermal images of a wound.* *The MSI does not diagnose or treat skin wounds.*	*…capturing thermal images to measure the thermal intensity data of a part of the body or two body surfaces…* *measure and record external wound and body surface data….* *…does not provide a diagnosis or therapy.*
Purpose:	An adjunctive tool that provides white light images, thermal images and wound area measurements for evaluation by a healthcare professional	An adjunctive tool that provides white light images, thermal images and wound area measurements for evaluation by a healthcare professional
Function:	Outputs: • White light image • Thermal image • Wound area measurement	Outputs: • White light image • Thermal image • Wound area measurement

Characteristic	MSI Kit Precision Healing LLC	WoundVision Scout WoundVision LLC K131596
Target Population:	Adult patients with wounds	Adult patients with wounds
Prescription Device:	Yes	Yes
Target Users:	Healthcare professionals who care for and treat patients with wounds	Healthcare professionals who care for and treat patients with wounds
Use Environment:	Point-of-care with patient (e.g., office or clinic)	Point-of-care with patient (e.g., office or clinic)

Comparison of the Technological Characteristics between the MSI Kit and the Predicate Devices

Both the MSI and the MolecuLight i:X share key core fluorescence functionality and technological characteristics (see Table 3). Both devices use overlapping excitation wavelengths to excite naturally occurring fluorophores in the wound and surrounding tissue, which in response emit light that is filtered and measured by a CMOS camera to produce an image. There is substantial overlap between the spectral profiles of the MSI and MolecuLight i:X's excitation LEDs. Specifically, the MSI uses a 395 nm light emitted from LEDs as the fluorescent excitation light whereas the predicate MolecuLight i:X uses a 405 nm light emitted from LEDs. MSI captures emission wavelengths > 450 nm whereas the predicate captures emission wavelengths from 500-545 nm and 600-665 nm. In both devices image processing occurs to produce fluorescence images. White light images are also collected. Any differences in technological characteristics do not raise different questions of safety or effectiveness compared to the predicate device.

For thermal imaging, the MSI and the WoundVision Scout predicate share very similar functionality and technological characteristics (see Table 4). Both devices use an infrared sensor to capture a thermal image of the wound. Both devices calculate a central tendency of temperature and use a color-coded display to produce a thermal image. Specifically, the MSI calculates the median temperature, and then uses a color coded scale to display the relative thermal image with a score of -4 to +4 °C from the median. WoundVision Scout calculates the mean temperature (rather than median) and uses a color-coded scale to display the relative thermal image. Both devices also provide white light images, and wound area measurements. Any differences in technological characteristics do not raise different questions of safety or effectiveness compared to the predicate device.

Table 3. Comparison of the Technological Characteristics of the MSI Kit to the MolecuLight i:X Predicate

Characteristic	**MSI Kit** **Precision Healing LLC**	**MolecuLight i:X** **MolecuLight Inc.** **DEN180008**
Operating Modes	Fluorescence, white light and thermal imaging	Fluorescence and white light imaging
Fluorescence Excitation Light	395 nm light emitted from LEDs	405 nm light emitted from LEDs
Captured Emission Wavelength	> 450 nm	500-545 nm and 600-665 nm
Fluorescence Output	• Red fluorescence • Green fluorescence • Blue fluorescence Images shown individually for each color.	• Red fluorescence • Green fluorescence All fluorescence features appear in the same image.
White Light Imaging	White light image is collected.	White light image is collected.
Working Distance	17-20 cm	8-12 cm (Fluorescence and Standard Imaging)
Image Format	JPEG	JPEG
Power Supply	Battery and wall	Battery and wall
Display	5” LCD	4-inch (diagonal) widescreen display with Multi-Touch IPS technology
Patient Contacting Materials	Non-patient contacting device	Non-patient contacting device
Sterile	No	No
Mechanical Safety	Compliance to IEC 60601-1	Compliance to IEC 60601-1
Electrical Safety	Compliance to IEC 60601-1	Compliance to IEC 60601-1
Electromagnetic Compatibility	Compliance to IEC 60601-1-2	Compliance to IEC 60601-1-2
Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57 IEC 62471 IEC 60825	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57 IEC 62471

Table 4. Comparison of the Technological Characteristics of the MSI Kit to the WoundVision Scout Predicate

Characteristic	**MSI Kit** **Precision Healing LLC**	**WoundVision Scout** **WoundVision, LLC** **K131596**
Operating Modes	Fluorescence, white light, thermal imaging, and wound area measurement	White light and thermal imaging, and wound area measurement
Infrared Laser Distance Finder Wavelength	940 nm	635 nm 650 nm
Infrared Laser Distance Finder Peak Power Output	< 0.4mW	< 0.4mW
Imaging/Optics	Thermal camera used to capture a thermal image of the wound	Thermal camera used to capture a thermal image of the wound
Image Processing	Median temperature is found. A color-coded scale is used to display the relative thermal image with a scale of -4 to +4 °C from the median.	Mean temperature is found. A color-coded scale is used to display the relative thermal image.
Function	Outputs: • Thermal image • White light image • Wound area measurement	Outputs: • Thermal image • White light image • Wound area measurement
Image Format	JPEG	PDF
Power Supply	Battery and wall	USB power from computer
Display	5” LCD on MSI	Displayed on computer
Patient Contacting Materials	Non-patient contacting device	Non-patient contacting device
Sterility	No	No
Mechanical Safety	Compliance to IEC 60601-1	Compliance to IEC 60601-1
Electrical Safety	Compliance to IEC 60601-1	Compliance to IEC 60601-1
Electromagnetic Compatibility	Compliance to IEC 60601-1-2	Compliance to IEC 60601-1-2
Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57 IEC 62471 IEC 60825	IEC 60601-1 IEC 60601-1-2 IEC 60825

Performance Data

This 510(k) notification provided performance data to establish the substantial equivalence of the MSI.

Reprocessing, Sterility and Shelf-Life: The MSI is not provided sterile and does not have direct patient contact. It is a reusable medical device. Reprocessing validation for cleaning and disinfection of the MSI has been conducted and the validated procedures are provided in the instructions for use. The MSI has undergone climatic conditions and transmit simulation (aka "ship testing") to demonstrate the adequacy of its packaging to protect the device during commercial shipment.

Biocompatibility: The MSI does not have direct patient contact. The MSI may contact intact skin surfaces of its users (healthcare professionals) for a limited duration of contact (≤ 24 hours), including repeat use. The MSI materials with potential direct contact of the intact skin of the user have a long history of safe use in medical devices, and pose a very low biocompatibility risk due to their history of safe use in medical devices.

Software Verification and Validation: Software verification and validation testing has been performed in accordance with IEC 62304 and the FDA guidance document for software. Verification and validation testing included unit test, system level verification tests (which included functional testing to demonstrate the device meet its requirements), traceability linking and validation testing to ensure the software conforms to user needs and intended uses.

Cybersecurity: Cybersecurity information in accordance with the FDA guidance document entitled "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions – Draft Guidance for Industry and Food and Drug Administration Staff," document issued on April 8, 2022, has been provided to demonstrate cybersecurity risks have been mitigated and that the risk of cybersecurity threats is deemed acceptable.

Electrical Safety and EMC Compatibility: The MSI has undergone testing to demonstrate that the device meets the requirements for medical device safety, including mechanical and electrical safety, according to the following international standards: IEC 60601-1, 3rd Edition, Medical electrical equipment – General requirements for basic safety and essential performance. The MSI has undergone testing to demonstrate the device meets the following international standard for EMC compatibility: IEC 60601-1-2, 4.1 Edition, Medical electrical equipment – Part 1-2, General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.

Performance Testing – Bench: A series of tests were performed to evaluate the safety and performance of the MSI.

Light Sources and Laser: Safety of the light sources (LEDs) and the laser were evaluated in accordance with the following standards:

- IEC 62471, First edition, 2006-07 Photobiological safety of lamps and lamp systems
- IEC 60825-1: 2014, Edition 3 Safety of laser products – Part 1: Equipment classification, and requirements
- IEC 60601-2-57: 2011, Edition 1, Medical electrical equipment – Part 2-57: Particular requirements for the basic safety and essential performance of non-laser

light source equipment for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

Visualization Performance Testing: A series of bench studies were conducted to verify the performance of the MSI Kit, including the following: image field uniformity, image distortion, field of view, magnification, geometric resolution, detection limits, linearity, signal-to-noise ratio, accuracy of thermal image data (at varied angles, distances and different cameras) and wound measurement area. A comparison of the performance of the MSI and MolecuLight for in vitro imaging for fluorescence was also performed.

Clinical Testing: A clinical study was conducted under anticipated conditions with anticipated users to evaluate the ability of the MSI to detect autofluorescence signals from tissues or structures consistent with the indications for use. These studies demonstrated the quality and consistency of the MSI images for their intended use of visualizing wounds.

Conclusion

The clinical and non-clinical data indicate that the MSI Kit is as safe and effective as the predicate devices for its indications for use, and is substantially equivalent.