December 22, 2023

Enspectra Health, Inc.
Grace Li
VP, Quality and Regulatory
2495 Hospital Dr, Suite 300
Mountain View, California 94040

Re: K232789
Trade/Device Name: VIO System (V-1000)
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical Lamp
Regulatory Class: Class II
Product Code: QZN
Dated: November 30, 2023
Received: November 30, 2023

Dear Grace Li:

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,

Colin K. Chen -S

for

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K232789

Device Name
VIO System (REF V-1000)

Indications for Use *(Describe)*
The VIO System is intended to acquire, store, retrieve, display and transfer in vivo images of tissue – including blood vessels, collagen, pigment, stratum corneum, hair shafts or follicles, solar elastosis, hyperkeratosis, atypia, and epidermal disarray – in and through epidermis for review by physicians to assist in forming a clinical judgment. Physicians who interpret VIO System images must have dermatology or pathology medical qualifications with skin histology assessment training.

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:

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*"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."*

Per 21 CFR 807.92, the following summary of information is provided:

**A. SUBMITTER**

Enspectra Health, Inc.
2495 Hospital Drive, Suite 300
Mountain View, California 94040

**Contact Person:**

Grace Li
VP, Quality and Regulatory
Enspectra Health, Inc.
Phone: (650) 480-6022

**Date Prepared:**

September 11, 2023

**B. DEVICE INFORMATION**

**Trade Name:**

VIO System

**Device Type/Common Name:**

Multi-photon imaging

**Classification Regulation:**

21 CFR§878.4580 Surgical Lamp

**Class:**

II

**Product Code:**

QZN: Multi-photon imaging

**C. PREDICATE DEVICE**

VivaScope System (Caliber Imaging & Diagnostics, K180162)
This predicate device has not been subject to a design related recall.
No reference devices were used in this submission.

## D. DEVICE DESCRIPTION

The VIO System (REF V-1000) is a light-based in vivo microscope intended to provide images of skin tissue for review by physicians to assist in forming a clinical judgment. The device does not provide image analysis or diagnostic information. The VIO System uses a handheld reflectance confocal and multiphoton microscope that contacts the skin and optically scans at a depth where most skin conditions originate, without disrupting the tissue.

The VIO System delivers low power laser light of a single wavelength (780 nm infrared, Class 1M) into the skin in brief pulses. The resulting signals are acquired while imaging the skin and each signal is assigned to one of four (4) channels:

| Channel | Description | Nominal Wavelength | Created primarily by |
|---|---|---|---|
| RCM | Reflectance Confocal Microscopy | 780 nm | Pigment and cellular membranes |
| SHG | Second Harmonic Generation | 390 nm | Collagen |
| 2PS | 2-Photon Autofluorescence Short | 450 nm | Cytoplasmic molecules and keratin |
| 2PL | 2-Photon Autofluorescence Long | 650 nm | Elastin and melanin |

For each image capture, the VIO System combines the four (4) channels to display a single, multi-color image on the VIO System, referred to as "Tetrachrome™." Three (3) view modes are accessible to the user on the VIO System:

| View Mode | Nominal Width | Nominal Depth | Description |
|---|---|---|---|
| Standard View | 0.4 mm | 0.3 mm | Complete area of scan |
| Superficial Zoom | 0.13 mm | 0.1 mm | Upper, center area of scan |
| Deep Zoom | 0.13 mm | 0.15 mm | Lower, center area of scan |

The view modes and vertical cross-sectional orientation of each image are comparable to the view through a standard light microscope of a physical glass slide using the 20x to 40x magnification setting.

Acquired images are not stored on nor analyzed by the VIO System. The images are saved on a USB flash drive, which is used to transfer images to a commercially available DICOM viewer for interpretation by a physician. For each image capture, the following files are produced:

| DICOM Label | File Type | Color |
|---|---|---|
| RGB (Red Green Blue) | DICOM, PNG | Tetrachrome (color composite) |
| RCM | DICOM | Grayscale |
| SHG | DICOM | Grayscale |
| 2PS | DICOM | Grayscale |
| 2PL | DICOM | Grayscale |

The VIO System has two (2) accessories, the VIO Imaging Cover (REF V-1100) and the VIO Targeting Sticker (REF V-1200). Both the VIO Imaging Cover and the VIO Targeting Sticker are single use accessories that are discarded after each use. Both accessories are provided nonsterile.

## E. INTENDED USE/INDICATIONS FOR USE

The VIO System and the predicate device have the same intended use; both are in vivo microscopes that use reflected light to capture images of the skin. The VIO System has the following indications for use:

> The VIO System is intended to acquire, store, retrieve, display and transfer in vivo images of tissue – including blood vessels, collagen, pigment, stratum corneum, hair shafts or follicles, solar elastosis, hyperkeratosis, atypia, and epidermal disarray – in and through epidermis for review by physicians to assist in forming a clinical judgment. Physicians who interpret VIO System images must have dermatology or pathology medical qualifications with skin histology assessment training.

The predicate device is intended to acquire, store, retrieve, display and transfer in vivo images of tissue, including blood, collagen and pigment, in exposed unstained epithelium and the supporting stroma. The differences in indications for use statements do not substantially modify the clinical information provided or the risk. The intended use to produce in vivo images of skin is the same between the subject and predicate devices.

## F. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological principle for both the subject and predicate devices is the use of reflected light to capture in vivo images of the skin. The subject and predicate devices use the following same technological elements:

- Single-point laser scanning Reflectance Confocal Microscopy (RCM) optical technology
- Illumination of unstained skin with near infrared wavelength and average power <35 mW

- Class 1M imaging laser
- Presentation of digital images with cellular detail
- DICOM image output

The differences in technological characteristics between the VIO System and the predicate device are:

- Optical Technology: The VIO System utilizes Multiphoton Microscopy (MPM) in addition to RCM to take in vivo pictures of skin.
- Image Presentation: The VIO System displays images in a vertical cross-sectional orientation in order to align orientation with traditional histopathology slides. The predicate device displays images in a horizontal orientation.
- Physical Design and Data Workflow: The VIO System is physically smaller and more flexible than the predicate device and has different patient contacting materials. The VIO System uses a USB flash drive to transfer data to a commercial DICOM viewer, while the predicate device is internet enabled with an embedded viewer.

## G. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

### Non-Clinical Performance Data

Non-clinical design verification and validation activities were completed for the VIO System based on risk analysis assessments and product requirements. Testing included verification and validation of specifications related to safety, usability, software, and performance, including the following:

- Electrical safety per ANSI AAMI ES60601-1:2005 +A1:2012 +A2:2021
- EMC per IEC 60601-1-2 Ed. 4.1
- Laser safety per IEC 60825-1 Ed 3.0
- Biological risk assessment per ISO 10993-1:2018
- Human factors assessment per IEC 62366-1:2015/Amd1:2020
- Software lifecycle management including software testing per IEC 62304 Ed 1.1
- Benchtop system imaging performance

Non-clinical performance testing confirmed that the VIO System met the predetermined acceptance criteria and demonstrated that the VIO System is safe and effective for its intended use. Non-clinical performance testing demonstrated that the differences between the subject and predicate devices do not raise different questions of safety or effectiveness.

**Clinical Performance Data**

A clinical study was conducted with N=65 participants to validate visualization of tissue structures by physicians to assist in forming a clinical judgment. In the study, the VIO System was used to image adults (18 years old and above) with Fitzpatrick Skin Type I-V, on skin lesions located on the head, neck, limbs, and torso.

Participants were randomly assigned to either a Training Set or Testing Set. N=3 Comparative Readers developed consensus training materials, then developed an answer key by validating VIO images against ground truth pathology. N=3 Blinded Readers (with dermatology or pathology medical qualifications and skin histology assessment training) were trained from Comparative Reader training materials, then tested on their ability to identify labeled structures in VIO images. The Blinded Reader performance test results are summarized in Table 1.

*Table 1. VIO System clinical performance test results*

| | **Blinded Reader Accuracy (95% CI)** |
|---|---|
| **Feature/Region** | |
| **None/Epidermis** | 96.0% (93.6% to 97.7%) |
| **Pigmented cell/Epidermis** | 93.5% (87.1% to 97.4%) |
| **None/Dermis** | 100% (91.0% to 100%) |
| **Collagen/Dermis** | 98.3% (96.7% to 99.3%) |
| **Pigmented cell/Dermis** | 95.6% (89.0% to 98.8%) |
| **Blood vessel/Dermis** | 87.2% (77.7% to 93.7%) |
| **Feature** | |
| **Stratum corneum** | 99.2% (97.1% to 99.9%) |
| **Hair shaft or follicle** | 97.8% (88.2% to 99.9%) |
| **Solar elastosis** | 99.1% (95.1% to 100%) |
| **Hyperkeratosis** | 100% (92.1% to 100%) |
| **Atypia** | 95.6% (84.9% to 99.5%) |
| **Epidermal disarray** | 100% (88.4% to 100%) |

The safety endpoint for the study was assessed: no adverse events were reported during the study. The effectiveness endpoint for the study was achieved as the results demonstrated overall >90% agreement between each Blinded Reader VIO image assessment and the answer key developed from the Comparative Reader validation assessment. The secondary endpoint of >90% inter-reader agreement was also achieved.

Clinical performance testing confirmed that the VIO System met the predetermined acceptance criteria and demonstrated that the VIO System is safe and effective for its intended use. Clinical performance testing demonstrated that the differences between the subject and predicate devices do not raise different questions of safety or effectiveness.

## H. CONCLUSION

The subject device and the predicate devices are both light-based in vivo microscopes. The VIO System has the same intended use and similar indications for use compared to the predicate device. In addition to single-photon excitation similar to the predicate device, the subject device also includes two-photon excitation to produce its images. The results of performance testing confirm that the VIO System functions pursuant to its specifications and intended use and exhibits the appropriate characteristics of a light-based in vivo microscope. Performance testing demonstrated that the differences between the subject and predicate devices do not raise new types of questions regarding safety and effectiveness. Thus, the VIO System is substantially equivalent to the predicate device, the VivaScope System (Caliber Imaging & Diagnostics, K180162).