DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 13, 2016

Perimeter Medical Imaging, Inc.
Elizabeth Munro
Engineering Operations and Regulatory Lead
156 Front Street West, Suite 501
Toronto, M5J 2L6 CA

Re: K160240
Trade/Device Name: Perimeter OTIS™ 1.0 Optical Coherence Tomography System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: NQQ
Dated: April 8, 2016
Received: April 11, 2016

Dear Elizabeth Munro:

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 and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the warnings section of the device's labeling:

> The safety and effectiveness of this device for diagnostic analysis (i.e. differentiating normal versus specific abnormalities) in any tissue microstructure or specified disease has not been evaluated."

Furthermore, the indication for use "the OTIS 1.0 Optical Coherence Tomography System is indicated for use as an imaging tool in the evaluation of excised human tissue microstructure by providing two-dimensional, cross-section, realtime depth visualization" must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

William H. Maisel -S

William H. Maisel, MD, MPH
Director (Acting)
Office of Device Evaluation
Deputy Center Director for Science
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160240

Device Name
OTIS 1.0 Optical Coherence Tomography System

Indications for Use *(Describe)*
The OTIS 1.0 Optical Coherence Tomography System is indicated for use as an imaging tool in the evaluation of excised human tissue microstructure by providing two-dimensional, cross-section, real-time depth visualization.

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.

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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."

SECTION 6

510(K) SUMMARY

510(k) Summary

1. Basic Information – Submitter

510(k) Owner: Perimeter Medical Imaging, Inc.

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Toronto, Ontario, Canada, M5J 2L6

Official Contact: Elizabeth Munro
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Date Summary Prepared: January 29, 2016

2. Device Name

Trade Name: Perimeter OTIS™ 1.0 Optical Coherence Tomography (OCT) System
Common Name: Optical Coherence Tomography (OCT) System
Classification Name: Ultrasonic pulsed echo imaging system
Regulatory Classification: 21 CFR 892.1560
Product Code: NQQ
Classification: Class II

3. Legally Marketed Predicate Devices

Imalux OCT Imaging System, K033783
Imalux Niris™ Imaging System, K042894

4. Device Description

The Perimeter Optical Tissue Imaging System (OTIS) 1.0 is an imaging tool for use on excised human tissue. The Perimeter OTIS is based on optical coherence tomography (OCT) imaging which is similar to ultrasound, but uses non-ionizing, low-power optical radiation to produce high resolution, sub-surface images of a tissue sample. Due to the extremely high velocity of light, optical echoes (reflected and backscattered light from the sample) cannot be measured directly using a photodetector. Instead, OCT devices use an interferometer to compare a reference beam of light to the backscattered light returning from the tissue sample. The features in an OCT image are created by changes in the optical properties (namely scattering, absorption, and index of refraction) of the sample.

The Perimeter OTIS collects and displays OCT images of human tissue with comparable image quality to other previously 510(k)-cleared OCT imaging systems. However, rather than requiring the clinician to move his/her hand to collect “point-by-point” images, the

Perimeter OTIS has automated the OCT scanning of the specimen surface, standardizing the image collection process.

The Perimeter OTIS also includes a white light image (e.g., photograph) of the specimen, to assist the clinician in viewing the OCT images with a reference to the white light image and the OCT image scan position. In addition, the Perimeter OTIS includes user interface options, such as the ability to "scroll" through the OCT images, across a specimen's surface, as well as to zoom and pan in more closely to examine areas of interest, as desired.

5. Intended Use

The OTIS 1.0 Optical Coherence Tomography System is indicated for use as an imaging tool in the evaluation of excised human tissue microstructure by providing two-dimensional, cross-sectional, real-time depth visualization.

6. Substantial Equivalence Summary

PRODUCT COMPARISON TABLE			
	Perimeter OTIS™ [New Device]	**Imalux Niris™ Imaging System [Predicate – K042894]**	**Imalux OCT Imaging System [Predicate – K033783]**
Measurement Technique	Optical Coherence Tomography	Optical Coherence Tomography	Optical Coherence Tomography
Center Wavelength [NIR: 700 – 1400 nm]	1325 ± 20 nm	1310 ± 15 nm	975 ± 15 nm
Optical Source	Super Luminescent Diode	Super Luminescent Diode	Super Luminescent Diode
Optical Radiation Safety	Safe for Indicated Use, Class 1 Laser	Safe for Indicated Use, Class 3R Laser	Safe for Indicated Use, Class 3R Laser
Lateral Resolution	≤ 50 µm	≤ 50 µm	≤ 50 µm
Lateral Range (x-axis): Single B-scan WF-OCT Scan	 (1.7 mm) 2 mm 500 mm [250 2 mm-strips]	 2 mm [Point-by-point by clinician]	 2 mm [Point-by-point by clinician]
Axial Resolution [free space units]	≤ 15 µm	≤ 15µm	≤ 15µm
In-depth tissue range [free space units]	1.5 mm in tissue [minimum of 2.2 mm in free space (7mm)]	1.5 mm in tissue [2.2 mm in free space]	1.5 mm in tissue [2.2 mm in free space]
Patient Applied Part	No Patient Applied Part	Handheld Fiber Optic Probe	Handheld Fiber Optic Probe
Input Devices: Keyboard Pointing Foot pedal (optional)	 Yes Yes No	 Yes Yes Yes - Optional	 Yes Yes Yes - Optional
Electrical Voltage Frequency	108-132 V, 60 Hz [North America Use]	90-132 V, 198-264 V 50/60 Hz	90-132 V, 198-264 V 50/60 Hz

7. Product and Quality Management Standards

The Perimeter OTIS was designed and developed under design controls per 21 CFR 820.30, in addition to risk management, ISO 14971:2007 Application of Risk Management to Medical Devices.

In addition, testing was performed to ensure that the Perimeter OTIS complies with the following recognized standards:

- IEC 60825-1:2014, Safety of Laser Products – Part 1: Equipment Classification and Requirements
- AAMI ANSI IEC 62304 Medical Device Software – Software Life Cycle Management
- AAMI ANSI ISO 15223-1:2012 Medical Devices – Symbols to be used with Medical Devices Labels, Labeling and Information to be Supplied – Part 1: General Requirements
- AAMI ANSI ISO 10993-1:2014 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process
- AAMI ANSI ES 60601-1: 2005/(R)2012, A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 Medical Electrical Equipment – Part 1 – General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2:2007 Medical Electrical Equipment Part 1-2: General Requirements for the Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

8. Technological Characteristics

The Perimeter OTIS is substantially equivalent to the Imalux Niris™ Imaging System [K042894] and the Imalux OCT Imaging System [K033783] as all three devices use the same technology, Optical Coherence Tomography, and have the same intended use.

The Perimeter OTIS provides a standardized “stepping” of the OCT image acquisition probe across a pre-set scan area (e.g., 3 cm – 5 cm). This stepwise Perimeter OTIS surface scanning is analogous to a clinician manually moving the Imalux fiber optic probe step-by-step and acquiring an OCT image at each new position. However, unlike the manual probe image acquisition of the predicate devices, the Perimeter OTIS performs this surface image acquisition by using an automated mechanical stage and precise probe positioning, without probe-tissue direct contact.

The Perimeter OTIS and the predicate devices use near infrared (NIR) light to produce Optical Coherence Tomography images. The Perimeter OTIS center wavelength is 1325 ± 20 nm, while the Imalux Niris™ Imaging System [K042894] center wavelength is 1310

± 15 nm, and the Imalux OCT Imaging System [K033783] center wavelength is 975 ± 15 nm. Both predicate devices use a detachable, fiber optic probe which requires the operator to place and hold the probe on the correct location during image acquisition. The Perimeter OTIS positions the probe automatically during imaging – reducing the operator workload and ensuring consistent sample coverage. While the method of probe positioning is different, the intended use of the predicate devices and the Perimeter OTIS are the same and a comparison of their respective technologies and functional characteristics shows that the Perimeter OTIS is at least as safe and effective as the predicate devices for this intended use.

9. Performance and Safety Testing

Perimeter completed verification and validation activities under Perimeter Design Control procedures to ensure that verification studies demonstrated that outputs met input requirements, and that validation studies demonstrated that the Perimeter OTIS fulfilled the intended use and user needs.

Perimeter validated the usability of the OTIS per IEC 62366:2007 – Application of usability engineering to medical devices. Testing was performed with representative users in actual and simulated use environments.

Perimeter validated that the OTIS can obtain OCT images with sufficient image quality to identify tissue microstructure features as compared to histopathology, at a level comparable to other OCT imaging systems.

External laser, electrical, and EMC testing successfully demonstrated the safety of the Perimeter OTIS in its intended environment. Perimeter OTIS employs a near infrared super luminescent diode for optical image acquisition, as well as a surface sensing laser system. Both laser systems are classified as Class 1 laser, per IEC 60825-1:2014, requiring no special optical safety precautions. This laser classification of Class 1 is a lower (safer) laser classification level than the predicate devices (Class 3R).

10. Conclusions

Perimeter Medical Imaging, Inc. has demonstrated that the OTIS™ 1.0 Optical Coherence Tomography System has the same intended use and is substantially equivalent to its predicate devices, the Imalux Niris™ Imaging System and the Imalux OCT Imaging System. The Perimeter OTIS also complies with recognized standards and guidelines for electrical safety, laser safety, and biocompatibility. Testing has demonstrated that the device is as safe, as effective, and performs as well or better than the predicate devices.