DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

August 25, 2017

Perimeter Medical Imaging, Inc.
Elizabeth Munro
Engineering Operations and Regulatory Lead
47 Colborne Street
Suite 202
Toronto, M5E 1P8 Ca

Re: K171560
Trade/Device Name: OTIS 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: May 25, 2017
Received: May 30, 2017

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 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 1B 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, with image review manipulation software for identifying and annotating regions of interest" 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 (DICE) 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 (DICE) 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,

William H. Maisel -S

William H. Maisel, MD, MPH
Acting Director, Office of Device Evaluation
Deputy Center Director for Science
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 5

INDICATIONS FOR USE STATEMENT

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)*
K171560

Device Name
OTIS 1B Optical Coherence Tomography System

Indications for Use *(Describe)*
The OTIS 1B 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, with image review manipulation software for identifying and annotating regions of interest.

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
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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.

Address: 47 Colborne Street, Suite 202
Toronto, Ontario, Canada, M5E 1P8

Official Contact**:** Elizabeth Munro
Engineering Operations and Regulatory Lead
Phone: 877-278-4614
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Date Summary Prepared: August 23, 2017

2. Device Name

Trade Name: Perimeter OTIS™ 1B 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

Perimeter OTIS™ 1.0 Optical Coherence Tomography (OCT) System, K160240

4. Device Description

The Perimeter OTIS 1B 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 1B collects and displays OCT images of human tissue with comparable image quality to other previously 510(k)-cleared OCT imaging systems and, specifically, the Perimeter OTIS 1.0 System (K160240). Like its predicate, the Perimeter OTIS 1B has automated the OCT scanning of the specimen surface, standardizing the image collection process.

The Perimeter OTIS 1B 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. The Perimeter OTIS 1B also 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. Indications for Use

The OTIS 1B 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 with image review manipulation software for identifying and annotating regions of interest.

6. Substantial Equivalence Summary

PRODUCT COMPARISON TABLE		
	Perimeter OTIS™ 1B [New Device]	**Perimeter OTIS™ 1.0 K160240 [Predicate]**
Measurement Technique	Optical Coherence Tomography	Optical Coherence Tomography
Center Wavelength [NIR: 700 – 1400 nm]	1325 ± 20 nm	1325 ± 20 nm
Optical Source	Super Luminescent Diode	Super Luminescent Diode
Optical Radiation Safety	Safe for Indicated Use, Class 1 Laser	Safe for Indicated Use, Class 1 Laser
Lateral Resolution (Nominal)	≤ 50 µm (20 µm)	≤ 50 µm
Lateral Range (x-axis): **Single B-scan** **WF-OCT Scan**	 (1.7 mm) 2 mm 500 mm [250 2 mm-strips]	 (1.7 mm) 2 mm 500 mm [250 2 mm-strips]
Axial Resolution (Nominal) **[free space units]**	≤ 15 µm (11.7 ± 2.0 µm)	≤ 15 µm
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 [minimum of 2.2 mm in free space (7mm)]
Patient Applied Part	No Patient Applied Part	No Patient Applied Part
Input Devices: **Keyboard** **Pointing** **Foot pedal (optional)**	 Yes Yes No	 Yes Yes No
Electrical Voltage Frequency	108-132 V, 60 Hz [North America Use]	108-132 V, 60 Hz [North America Use]

As the OTIS 1B device is identical in construction to OTIS 1.0, the Systems may be collectively refer to as “OTIS Systems.”

7. Product and Quality Management Standards

The Perimeter OTIS Systems were 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 System 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 1B is substantially equivalent to the Perimeter OTIS 1.0 [K160240] as the devices are identical and have the same intended use.

Both Perimeter OTIS Systems provide a standardized “stepping” of the OCT image acquisition probe across a pre-set scan area (e.g., 3 cm – 5 cm). The Perimeter OTIS Systems perform this surface image acquisition by using an automated mechanical stage and precise probe positioning.

The Perimeter OTIS 1B and the predicate device, OTIS 1.0, use near infrared (NIR) light to produce Optical Coherence Tomography images. The Perimeter OTIS Systems have a center wavelength of 1325 ± 20 nm. The Perimeter OTIS Systems position the probe automatically during imaging – reducing the operator workload and ensuring consistent

sample coverage. The intended use of the Perimeter OTIS 1B is the same as OTIS 1.0; the indications for use for OTIS 1B are encompassed within the intended use of the OTIS Systems; and the device constructions are identical. Therefore, Perimeter OTIS 1B is as safe and effective as the predicate device.

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 Systems 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 1B can obtain OCT images with sufficient image quality to identify excised 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 Systems in its intended environment. Perimeter OTIS Systems employ 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.

10. Conclusions

Perimeter Medical Imaging, Inc. has demonstrated that the OTIS 1B Optical Coherence Tomography System has the same intended use and is substantially equivalent to its predicate devices, the OTIS™ 1.0 Optical Coherence Tomography System. The Perimeter OTIS 1B, as it is identical in construction to the OTIS 1.0, complies with recognized standards and guidelines for electrical safety, laser safety, and biocompatibility. Testing has demonstrated that the devices is as safe and effective as the predicate device.