Perimeter Medical Imaging AI, Inc.
℅ Cindy Domecus
Regulatory Consultant
Domecus Consulting Services, LLC
1171 Barroihet Avenue,
Hillsborough, California 94010

February 25, 2021

Re: K203578
Trade/Device Name: OTIS 2.1 Optical Coherence Tomography System, THiA 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: January 29, 2021
Received: February 1, 2021

Dear Cindy Domecus:

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. 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 located 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.

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

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 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,

Neil R.P. Ogden
Assistant Director, THT4A4
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.

510(k) Number *(if known)*
K203578

Device Name
OTIS 2.1 Optical Coherence Tomography Imaging System

Indications for Use *(Describe)*
The OTIS 2.1 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.

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K203578

510(k) Summary

1. Basic Information – 510(k) Owner

510(k) Owner:	Perimeter Medical Imaging AI, Inc.
Address:	359 Eastern Avenue, Suite 110 Toronto, Ontario, Canada Phone: 647-360-0302
Official Contact:	Cindy Domecus, R.A.C. (US & EU) Principal Domecus Consulting Services LLC DomecusConsulting@comcast.net
Date Summary Prepared:	December 3, 2020

2. Device Name

Trade Name: Perimeter OTIS™ 2.1 and THiA™

Common Name: Optical Coherence Tomography 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™ 2.0, K190404

4. Device Description

The Perimeter OTIS™ 2.1 is an imaging tool for use on excised human tissue. The Perimeter OTIS™ 2.1 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™ 2.1 collects and displays OCT images of human tissue with comparable image quality to the predicate Perimeter OTIS 2.0 System (K190404). Like its predicate, the Perimeter OTIS™ 2.1 has automated the OCT scanning of the specimen surface, standardizing the image collection process and facilitating image manipulation for review and annotation. OTIS 2.1 allows for the concurrent image review and acquisition.

5. Indications for Use

The OTIS™ 2.1 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. Predicate Device Comparison

Characteristic	Perimeter OTIS™ 2.1 [Subject Device]	Perimeter OTIS™ 2.0 [Predicate Device]
Intended Use	Imaging tool in the evaluation of human tissue microstructure by providing two-dimensional, cross-sectional, real-time depth visualization.	Same
Indications for Use	The OTIS 2.1 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.	Same
Measurement Technique	Optical Coherence Tomography	Same
Center Wavelength	1325 ± 15 µm	Same
Optical Source	Super Luminescent Diode	Same
Optical Radiation Safety	Safe for Indicated Use Class 1 Laser	Same
Lateral Resolution	20 µm	Same
Lateral Range	870 mm	Same
Axial Resolution	10 – 15 µm in tissue	Same
Scan Acquisition Time	< 1 minute [5 x 5 cm area]	Same
Input Devices	Touchscreen	Same

Characteristic	Perimeter OTIS™ 2.1 [Subject Device]	Perimeter OTIS™ 2.0 [Predicate Device]
Electrical Voltage Frequency	108 – 132 V, 60 Hz [North American Use]	Same

7. Product and Quality Management Standards

The OTIS™ 2.1 was designed and developed under design controls per 21 CFR 820.30 and ISO 13485:2016. The following standards were followed:

- ANSI AAMI ISO 14971:2007/(R)2010 (Corrected 4 October 2007) Medical Devices – Applications of Risk Management to Medical Devices
- AAMI ANSI ES 60601-1:2005/(R)2012, A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 Medical Electrical Equipment – Part 1, Basic Safety and Essential Performance
- IEC 60601-1-2 Edition 4.0 2014-02 Medical Electrical Equipment Part 1-2: General Requirements for the Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests
- IEC 60825-1:2007, Safety of Laser Products – Part 1 Equipment Classification and Requirements
- ANSI AAMI ISO 10993-1:2009/(R)2013 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing with a Risk Management Process
- ANSI AAMI ISO 10993-5:2009/(R)2014, Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity
- IEC 62304:2006/A1:2015 Medical Device Software – Software Life Cycle Processes AAMI ANSI ES 60601-1:2005 – Basic Safety and Essential Performance

8. Technological Characteristics

The subject of this Special 510(k) submission is a device enhancement to provide an updated version of the predicate OTIS 2.0 device that has a smaller cart foot print, a faster PC, design improvements for manufacturability, component updates to address obsolescence and ensure longer useful life of the product and optimized image acquisition and processing, graphical user improvements for streamlined user experience with consistent screen displays.

These updates do not affect the intended use or alter the fundamental scientific technology of the predicate device.

9. Performance and Safety Testing

Perimeter completed verification and validation activities under Perimeter's Design Control procedure. This ensured that verification studies demonstrated that outputs met design input requirements, and that validation studies demonstrated that the Perimeter OTIS™ 2.1 fulfilled the intended use and met user needs.

Design verification and validation testing for OTIS 2.1 was carried out using the same test protocols/methodology as was used to test OTIS 2.0. Established testing against the same ISO/IEC standards as applicable for OTIS 2.0, was conducted as follows:

- Biocompatibility testing of the Consumable Set per ISO 10993-1:2009/(R)2013 and IS0 10993-5:2009/(R)2014.

- External laser, basic safety and electromagnetic compatibility testing successfully demonstrated the safety of OTIS™ 2.1 in its intended environment.

10. Conclusions

Perimeter's OTIS 2.1 has the same intended use, indications for use, principles of operation and same technological characteristics as compared to the predicate device. The minor differences implemented in the OTIS 2.0 platform to create OTIS 2.1 do not raise different questions of safety and effectiveness.

Design verification and validation testing demonstrates that OTIS 2.1 Optical Coherence Tomography Imaging System is as safe and effective as the predicate device and is substantially equivalent to OTIS 2.0.