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...
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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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. Ogden -S

Digitally signed by Neil R. Ogden -S
Date: 2019.03.26 13:52:07 -04'00'

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
### Indications for Use (Describe)

The OTIS 2.0 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, with image review manipulation software for identifying and annotating regions of interest.

### Type of Use (Select one or both, as applicable)

- [x] 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
- PRASStaff@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

1. Basic Information – 510(k) Owner
510(k) Owner: Perimeter Medical Imaging, Inc.
Address: 1 Yonge Street, Suite 201
Toronto, Ontario, Canada
Phone: 647-360-0302
Official Contact: Cindy Domecus, R.A.C. (US & EU)
Principal Domecus Consulting Services LLC
Date Summary Prepared: March 13, 2019

2. Device Name
Trade Name: Perimeter OTIS™ 2.0
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™ 1B, K171560

4. Device Description
The Perimeter OTIS™ 2.0 is an imaging tool for use on excised human tissue. The Perimeter OTIS™ 2.0 is based on optical coherence tomography (OCT) imaging, and it 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™ 2.0 collects and displays OCT images of human tissue with comparable image quality to other previously 510(k)-cleared OCT imaging systems and, specifically, the predicate Perimeter OTIS 1B System (K171560). Like its predicate, the Perimeter OTIS™ 2.0 has automated the OCT scanning of the specimen surface, standardizing the image collection process.

The Perimeter OTIS™ 2.0 includes a white light image (photograph) of the specimen, to assist the clinician in viewing the OCT images with a reference to the photograph and the OCT image scan position. The Perimeter OTIS™ 2.0 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™ 2.0 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

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Perimeter OTIS™ 2.0 [Subject Device]</th>
<th>Perimeter OTIS™ 1B [Predicate Device]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use</td>
<td>Imaging tool in the evaluation of human tissue microstructure by providing two-dimensional, cross-sectional, real-time depth visualization.</td>
<td>Same</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>The OTIS 2.0 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, with image review manipulation software for identifying and annotating regions of interest.</td>
<td>Same</td>
</tr>
<tr>
<td>Measurement Technique</td>
<td>Optical Coherence Tomography</td>
<td>Same</td>
</tr>
<tr>
<td>Center Wavelength</td>
<td>1325 ± 15 µm</td>
<td>Same</td>
</tr>
<tr>
<td>Optical Source</td>
<td>Super Luminescent Diode</td>
<td>Same</td>
</tr>
<tr>
<td>Characteristic</td>
<td>Perimeter OTIS™ 2.0 [Subject Device]</td>
<td>Perimeter OTIS™ 1B [Predicate Device]</td>
</tr>
<tr>
<td>------------------------</td>
<td>--------------------------------------</td>
<td>---------------------------------------</td>
</tr>
<tr>
<td>Optical Radiation Safety</td>
<td>Safe for Indicated Use Class 1 Laser</td>
<td>Same</td>
</tr>
<tr>
<td>Lateral Resolution</td>
<td>20 µm</td>
<td>Same</td>
</tr>
<tr>
<td>Lateral Range</td>
<td>870 mm</td>
<td>500 mm</td>
</tr>
<tr>
<td>Axial Resolution</td>
<td>10 – 15 µm in tissue</td>
<td>Same</td>
</tr>
<tr>
<td>Scan Acquisition Time</td>
<td>&lt; 1 minute [5 x 5 cm area]</td>
<td>&lt; 12 minutes [5 x 5 cm area]</td>
</tr>
<tr>
<td>Input Devices</td>
<td>Touchscreen</td>
<td>Mouse and Keyboard</td>
</tr>
<tr>
<td>Electrical Voltage</td>
<td>108 – 132 V, 60 Hz [North American Use]</td>
<td>Same</td>
</tr>
</tbody>
</table>

7. Product and Quality Management Standards

The OTIS™ 2.0 was designed and developed under design controls per 21 CFR 820.30 and ISO 13485:2003. The following standards were followed:

- NEMA PS 3.1 – 3.2 (2016) Digital Imaging and Communications In Medicine (DICOM) Set
8. Technological Characteristics

The Perimeter OTIS™ 2.0 is substantially equivalent to the Perimeter OTIS™ 1B [K171560] as the devices use the same technology, Optical Coherence Tomography, and have the same intended use.

The Perimeter OTIS™ 2.0 and the predicate device both use near infrared light to produce OCT images. The Perimeter OTIS™ systems have a center wavelength of 1325 nm and comparable axial and lateral resolution.

Both the OTIS™ 2.0 and OTIS™ 1B provide a standardized “stepping” of the OCT image acquisition across a user-selected scan area. The Perimeter OTIS™ systems perform this surface image acquisition by using an automated mechanical stage and precise probe positioning – reducing operator workload and ensuring consistent sample coverage, versus conventional hand-held OCT imaging devices. The Perimeter OTIS™ 2.0 offers a 10x improvement in image acquisition speed versus the predicate OTIS™ 1B.

The technological characteristics are comparable and don’t raise different questions of safety or effectiveness.

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™ 2.0 fulfilled the intended use and met user needs.

Perimeter validated the usability of the OTIS™ 2.0 per IEC 62366:2015 – Application of usability engineering to medical devices. Testing was performed with representative users in a simulated use environment.

Perimeter validated that the OTIS™ 2.0 can obtain OCT images with sufficient image quality to identify excised tissue microstructure features, at a level comparable to other OCT imaging systems, including the predicate device, OTIS 1B.

External laser, basic safety and electromagnetic compatibility testing successfully demonstrated the safety of OTIS™ 2.0 in its intended environment. OTIS™ 2.0 is classified as a class 1 laser per IEC 60825-1:2007, requiring no special optical safety precautions.
10. Conclusions

Perimeter Medical Imaging, Inc., has demonstrated that the OTIS™ 2.0 Optical Coherence Tomography System has the same intended use, and is substantially equivalent to its predicate device, the OTIS™ 1B Optical Coherence Tomography System. The Perimeter OTIS™ 2.0 also complies with recognized standards and guidelines for electrical safety, laser safety, and biocompatibility. Testing has demonstrated that the device is as safe and effective and performs as well or better than the predicate device.