



March 8, 2024

Cylite Pty Ltd
% Lena Sattler
President
Orasi Consulting
226 1st Street
Bonita Springs, Florida 34134

Re: K231760
Trade/Device Name: HP-OCT
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO
Dated: February 3, 2024
Received: February 5, 2024

Dear Lena Sattler:

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,

Elvin Y. Ng -S

Elvin Ng

Assistant Director

DHT1A: Division of Ophthalmic Devices

OHT1: Office of Ophthalmic, Anesthesia,

Respiratory, ENT and Dental Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K231760

Device Name

HP-OCT

Indications for Use (Describe)

The HP-OCT™ instrument is a non-contact ophthalmic imaging and analysis device. It is indicated for visualization of the posterior segment of the eye.

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.

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510(k) Summary

1. General Information

Manufacturer:	Cylite Pty Ltd 300 Wellington Road Mulgrave Victoria 3170 Australia +61-3-95812601
Sponsor Contact Person:	Arnold Ouyang VP Quality & Regulatory 300 Wellington Road Mulgrave Victoria 3170 Australia
Official Correspondent:	Lena Sattler President, Orasi Consulting 226 1 st street Bonita Springs, FL 34134
Date Prepared:	March 5, 2024
Device Information:	
Classification Name:	Tomography, Optical Coherence
Trade/Propriety Name:	HP-OCT™
Common Name:	Optical Coherence Tomography
Regulation Number:	21 CFR 886.1570
Device class:	II
Product Code:	OBO

2. Predicate Device

Company:	Carl Zeiss Meditec, Inc.
Device:	Cirrus HD-OCT 5000 (K181534)

The subject device and predicate device are both intended for non-contact imaging and analysis of ocular structures. Both devices are indicated for posterior segment visualization. The additional indications for use (IFU) offered by the predicate device do not change the intended use.

3. Device Description

The Cylite Hyperparallel Optical Coherence Tomographer (HP-OCT) is an ophthalmic OCT system, intended to assist ophthalmic professionals in the diagnosis of ophthalmic conditions via non-contact imaging of the posterior segment. OCT imaging is accomplished in the HP-OCT instrument using a micro-lens array to separate the illumination from a super-luminescent diode (SLD) source into an array of parallel beamlets. The beamlet array is then projected simultaneously onto the eye. Each of the individual beamlets is equivalent to a single beam of an SD-OCT (Spectral Domain OCT) system. Each beamlet generates a spectral interferogram, equivalent to a single SD-OCT interferogram, which is processed to produce an individual A-scan. A set of 1008 parallel, SD-OCT type A-scans is thus acquired for each frame of the CMOS sensor, and multiple frames can be acquired to create dense volume images.

The HP-OCT instrument is supplied with an exchangeable lens which supports OCT imaging of the posterior segment.

The HP-OCT instrument is operated from the Cylite Focus software that runs from a Windows 10 personal computer (PC) supplied by the user. The PC hosts the HP-OCT Capture and Focus Review software and connects to the HP-OCT instrument via a USB 3.0/3.1 cable. From the PC/software, the user employs the PC monitor, keyboard and mouse to interact with the HP-OCT instrument to perform instrument alignment, preview images, capture images, save or load image or patient data, review images, and manage patient data.

4. Indications for Use

The HP-OCT™ instrument is a non-contact ophthalmic imaging and analysis device. It is indicated for visualization of the posterior segment of the eye.

5. Technological Comparison

The HP-OCT instrument and the predicate device Cirrus HD-OCT 5000 are both mains powered and examine the ocular structures by projecting measurement and/or illumination lights onto the eye and then collecting/analyzing the returning signals.

Both devices employ the same SLD light source with a wavelength spectrum centered at 840nm to generate an A-scan based on the same SD-OCT (Spectral Domain OCT) principle. Cirrus HD-OCT 5000 scans a single beam onto different locations over a short period of time to generate the A-scans that constitute a B-scan or C-scan, while the HP-OCT instrument projects and scans a grid of beamlets onto the eye surface at the same time and constructs C-scans from the A-scans generated by the individual beamlets. Both devices utilize the chin/head rest to facilitate positioning the patient's head for optical imaging. The body contact profiles are the same. No sterilization is required.

Other differences in the device technological characteristics include the following.

- Although both devices employ LED for fixation/alignment illumination, the subject and predicate devices use different LEDs with different wavelengths. These differences in these LED wavelengths do not raise different questions of safety and effectiveness.
- While the range of technical specifications (e.g. acquisition rate, scan/imaging range/coverage, resolutions) of the subjective HP-OCT instrument are not exactly the same as the predicate device, the differences in ranges do not raise different questions of safety and effectiveness.

Table 1 - Summary of Comparison between HP-OCT and the Predicate Device

Characteristics	Subject device Cylite HP-OCT	Predicate device Zeiss Cirrus 5000 HD-OCT	Comparison
510(k) number	K231760	K181534	N/A
Regulation	21CFR 886.1570	21CFR 886.1570	Same
Class	II	II	Same
Intended use	Non-contact imaging and analysis of ocular structures	Non-contact imaging and analysis of ocular structures	Same
Indications for use (IFU)	The HP-OCT™ instrument is a non-contact ophthalmic imaging and analysis device. It is indicated for visualization of the posterior segment of the eye.	CIRRUS™ HD-OCT is a non-contact, high resolution tomographic and biomicroscopic imaging device intended for in-vivo viewing, axial cross-sectional, and three-dimensional imaging of anterior and posterior ocular structures. The device is indicated for visualizing and measuring anterior and posterior ocular structures, including cornea, corneal epithelium, retina, retinal nerve fiber layer, ganglion cell plus inner plexiform layer, macula, and optic nerve head. The CIRRUS normative databases are quantitative tools indicated for the comparison of retinal nerve fiber layer thickness, macular thickness, ganglion cell plus inner plexiform layer thickness, and optic nerve head measurements to a database of normal subjects. CIRRUS' AngioPlex OCT Angiography is indicated as an aid in the visualization of vascular structures of the retina and choroid. (Model 5000 only.) CIRRUS HD-OCT is indicated as a diagnostic device to aid in the detection and management of ocular diseases including, but not limited to, macular holes, cystoid macular edema, diabetic retinopathy, age-related macular degeneration, and glaucoma.	Different – Both devices support posterior segment imaging. The predicate device provides automated measurements of anterior and posterior ocular structures. The subject device does not provide automated measurements of any ocular parameters.
Imaging method	Spectral Domain OCT – C scan from multiple A scans generated from a grid of beamlets being simultaneously projected onto the eye	Spectral Domain OCT – B/C scan from multiple A scans generated from the single beam being scanned over the eye in a short period of time	Similar – The same OCT operating principle. Different A-scan acquisition methods do not raise different questions of safety or effectiveness.
Measurement light source	Superluminescent Diode (SLD), 840 nm	Superluminescent Diode (SLD), 840 nm	Same
Fixation/alignment light source	LED – White (6500 K), Red (633 nm), IR (940 nm)	LED – 523 nm, 627 nm	Different – Different LED light wavelengths in auxiliary functions (fixation and alignment) do not raise different questions of safety or effectiveness.
Acquisition rate	>300K A-scans/second	68k A-scans/second	Different – Higher acquisition rate of the subject device does not raise different questions of safety or effectiveness.

Characteristics	Subject device Cylite HP-OCT	Predicate device Zeiss Cirrus 5000 HD-OCT	Comparison
Axial resolution	9.0 μm (in tissue)	5 μm (in tissue) ¹	Different – Imaging resolutions are not exactly same but the differences do not raise different questions of safety or effectiveness.
Lateral resolution (retina)	19 μm	15 μm ¹	Different – Imaging resolutions are not exactly same but the differences do not raise different questions of safety or effectiveness.
Retinal coverage (field of view)	9.4 x 5.4 mm	6 mm square grid ¹	Different – Wider coverage of the subject device does not raise different questions of safety or effectiveness.
Patient contacting parts	Chin and head rest	Chin and head rest	Same
Skin contact duration (typical)	< 24 hours	< 24 hours	Same
Reusable	Yes	Yes	Same
Sterile	No	No	Same
Rated voltage / frequency	100 V to 240 V AC ($\pm 10\%$) / 50/60 Hz	100-120 V~ 50-60 Hz 6.3A 220-240 V~ 50-60 Hz 3.15A	Similar
Transportation conditions	Temperature: 0°C to +45°C Relative Humidity: 10% to 95%	Temperature: -40°C to +70°C, Relative humidity: 10% to 100%	Similar – No impact on clinical performance or safety when used in the recommended conditions.

¹ Cirrus HD-OCT 5000 user manual

6. Performance Test Summary

6.1 Non-clinical performance testing

Non-clinical performance bench tests have been conducted on the HP-OCT instrument to demonstrate the substantial equivalence to the predicate device, including,

- Optical imaging performances including resolution, field of view, axial range, signal-to-noise ratio and depth attenuation.
- Optical safety tests and assessments in accordance with the following international and consensus standards
 - ISO 15004-1:2020 - Ophthalmic instruments – Fundamental requirements and test methods– Part 1: General requirements applicable to all ophthalmic instruments
 - ISO 15004-2:2007 - Ophthalmic Instruments – Fundamental requirements and test methods – Part 2: Light hazard protection
 - ANSI Z80.36:2021 - American National Standard for Ophthalmics - Light Hazard Protection for Ophthalmic Instruments
- Electrical, mechanical and thermal safety tests in accordance with the following international and consensus standards
 - IEC 60601-1:2005/A1:2012 - Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
 - ANSI/AAMI ES60601-1:2005/(R)2012 - Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
- Electromagnetic compatibility tests in accordance with the following consensus standard
 - IEC 60601-1-2:2014/A1:2020 - Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- Biocompatibility tests in accordance with the following international and consensus standards
 - ISO 10993-1:2018 - Biological evaluation of medical devices - Part 1 Evaluation and testing within a risk management process
 - ISO 10993-5:2009 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
 - ISO 10993-10:2010 - Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.
- Software verification and validation tests as a “Moderate” level of concern in accordance with FDA’s guidance “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”. The development of the software also complied with the consensus standard IEC 62304:2015 -Medical Device Software life-cycle processes.
- Human factors validation (usability summative evaluation) in accordance with FDA guidance “Applying Human Factors and Usability Engineering to Medical Devices” and the consensus

standard IEC 62366-1:2020 - Medical devices - Part 1: Application of usability engineering to medical devices.

6.2 Clinical Performance Testing

A clinical study was conducted at three sites to validate clinical performance of the HP-OCT. The clinical study was performed to investigate the reliability of the HP-OCT in generating retinal images to aid qualitative diagnosis as compared to the predicate device Cirrus HD-OCT 5000 (K181534).

The study recruited two groups of subjects, subjects with normal eyes and subjects with retinal diseased eyes into the study. The scan types employed were HP-OCT – Retina and Cirrus HD-OCT 5000 – Macular Cube.

Both eyes of the same subject could be enrolled in different eye groups if the corresponding eligibility criteria was satisfied. If both eyes of a subject were eligible for the same eye group, the study eye was randomly determined. A total of 83 eyes (43 normal eyes, 40 retina diseased eyes) were enrolled in this study. The age range was 19 to 66 years in Normal group with a mean of 36.5 (+/-12.6) years and a median of 33 years. The Retinal Disease group had a mean age of 69.9 (+/-12.2) years and a median age of 73.5 years, with the range between 25-85 years. Majority of the subjects were female in Normal (86%). In Retinal Disease group, the male subjects (53%) were slightly more than female ones (47%). White (49%) and Asian (49%) subjects were evenly distributed in the Normal group and a higher percentage of Whites was in the Retinal Disease group (77.5%).

Data Collection

The study employed three HP-OCT and three Cirrus HD-OCT 5000. Each of the three sites possessed one pair of the two devices, one HP-OCT and one Cirrus HD-OCT (two device units in total at a site) to perform the study.

All eligible eyes underwent non-contact ocular scans using the HP-OCT and Cirrus HD-OCT 5000 in a single site visit. The order of scan devices and scan types were randomized. All imaging activities for a subject were taken by one operator in a single visit. The scans which satisfied the imaging quality criteria according to the study protocol (and respective operator manuals) were deemed acceptable.

After imaging, the first acceptable retinal image acquired on the HP-OCT and the Cirrus HD-OCT 5000 for each eligible subject were sent to an image reading center for retinal image grading by three independent graders. The image graders were masked to subject identification, eye group allocation, eye examination results and each other's grading results. For each image, the image grader attempted to identify 9 anatomic structures and 11 abnormalities which were pre-defined and scored 1 (if identifiable) or 0 (if unidentifiable) for each structure/abnormality.

Data Analysis

The subjective grade score (SGS) as the sum of individual scores was then calculated for structure (maximum 9) and abnormality (maximum 11), respectively. The analyses performed included the

mean, standard deviation, median, maximum, and minimum of SGS differences between HP-OCT and Cirrus HD-OCT 5000, two-sided Wilcoxon Signed-Rank test of SGS differences between devices and graders respectively, agreement rate of the same score for the two devices for each structure and abnormality, and the inter-grader difference for HP-OCT for each structure and abnormality. These analyses were performed by eye groups.

Results

No adverse effects were observed or reported.

For the identification of anatomic structures and key retinal abnormalities, the results of the clinical performance testing demonstrate a favorable clinical performance profile that supports a determination of substantial equivalence. The grading results of overall SGS support a determination of substantial equivalence for the two devices in Normal and Retinal Disease eyes.

7. Conclusion

Comparison of intended use and technological characteristics and evaluation of non-clinical testing and clinical performance data support the substantial equivalence of the HP-OCT subject device to the predicate device Cirrus HD-OCT 5000 for the indications for use.