February 28, 2018

Optos plc
Geoff Fatzinger
VP of Global Regulatory Affairs
Queensferry House, Carnegie Business Campus,
Dunfermline, KY118GR Gb

Re: K173707
Trade/Device Name: P200TE
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO, HLI, MYC
Dated: November 29, 2017
Received: December 4, 2017

Dear Geoff Fatzinger:

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. 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); 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.

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.

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 yours,

Bradley S. Cunningham -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173707

Device Name
P200TE

Indications for Use *(Describe)*
The P200TE is a non-contact scanning laser ophthalmoscope and optical coherence tomographer intended for in-vivo viewing and digital imaging of posterior ocular structures, including the retina, retinal nerve fiber layer and optic disc. It is indicated for producing high-resolution, widefield, en face reflectance images, autofluorescence images, and axial, cross-sectional images of the posterior ocular structures.

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

This summary of the 510(k) premarket notification for the Optos P200TE is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR§807.92.

Date Prepared: February 20, 2018

SPONSOR/ 510(k) OWNER/ MANUFACTURER

Optos plc
Queensferry House
Carnegie Campus
Enterprise Way
Dunfermline
Scotland KY11 8GR
United Kingdom

CONTACT PERSON

Geoff Fatzinger
Optos plc
Vice President of Regulatory
Ph – +44 (0)7741 312633
Email – gfatzinger@optos.com

NAME OF DEVICE

Model Number: P200TE
Classification Name: Tomography, Optical Coherence Ophthalmoscope

DEVICE CLASSIFICATION

Class II A/C Powered Ophthalmoscope

PRODUCT CODE: CLASSIFICATION / CFR TITLE

OBO, HLI / 21 CFR 886.1570

PREDICATE DEVICES

Primary Predicate: Optos Spectral OCT/SLO (K080460)
Secondary Predicate: Optos P200DTx (K142897)

INDICATIONS FOR USE

The P200TE is a non-contact scanning laser ophthalmoscope and optical coherence tomographer intended for in-vivo viewing and digital imaging of posterior ocular

structures, including the retina, retinal nerve fiber layer and optic disc. It is indicated for producing high-resolution, widefield, en face reflectance images, autofluorescence images, and axial, cross-sectional images of the posterior ocular structures.

PRODUCT DESCRIPTION

The P200TE is based on Scanning Laser Ophthalmoscope (SLO) technology which scans in two dimensions over the retina. Light reflected from the retina is detected and transformed into a digital image. Images may be stored and subsequently reviewed.

The P200TE allows images to be captured in the following imaging modes:

- Reflectance imaging
- Autofluorescence imaging
- Optical coherence tomography imaging

The P200TE instrument uses red and green laser illumination for reflectance imaging, enabling it to image pathology throughout the layers of the retina, from the sensory retina and nerve fiber layer, through the retinal pigment epithelium (RPE) and down to the choroid. The image can be separated to present the distinct retinal sub-structures associated with the individual imaging wavelengths.

The P200TE instrument uses green laser illumination to excite autofluorescence (AF) emission from the naturally occurring lipofuscin in the human fundus.

The P200TE instrument uses infrared laser illumination for reflectance imaging simultaneously with OCT imaging. Infra-red reflectance images are used to track eye position during OCT imaging and are not available to the user. The P200TE instrument uses infrared superluminescent diode (SLD) illumination for optical coherence tomography allowing a depth profile of the reflectance of the human fundus to be recorded.

The P200TE images the eye via two ellipsoidal mirrors arranged so that a focal point of one of the mirrors coincides with a focal point of the other mirror; a mirrored scanner is also located at this common focal point. The pupil of the subject's eye is placed at one of the other focal points. A second mirrored scanner is located at the remaining focal point; a laser or SLD

reflected off this scanner is relayed onto the second scanner by the first ellipsoidal mirror and from there is reflected through the pupil and into the eye by the second ellipsoidal mirror. The second scanning element is different for OCT and SLO imaging. The energy reflected back from the retina, or emitted by fluorophores returns through the same path to the detectors; the images are generated from the captured detector data.

This is operationally installed to be networked with computer peripherals and proprietary software that facilitate the storage, management and viewing of the retinal images. The images are captured by the scan head under operator control and then automatically saved to the image server that uses a database structure to hold the images and patient information. For subsequent image review, a number of viewing PC's are connected via a local area network to the
image server. The patient records and images are then accessible in a distributed format suited to the physical layout of the eye-care practice.

SUBSTANTIAL EQUIVALENCE

The company's P200TE is substantially equivalent to the Optos Spectral OCT/SLO cleared in K080460 with additional equivalence to the Optos P200DTx cleared in K142897**.** As explained in more detail below, the P200TE has the same intended use and similar principles of operation and technological characteristics as the previously cleared predicate devices**.** See the table below for a substantial equivalence chart comparing the relevant similarities and differences between the P200TE and its predicates:

Device	OPTOS P200TE	Primary: Spectral OCT/SLO	Secondary: OPTOS P200DTx
510(k) Number	K173707	K080460	K142897
Indications For Use	The P200TE is a non-contact scanning laser ophthalmoscope and optical coherence tomographer intended for in-vivo viewing and digital imaging of posterior ocular structures, including the retina, retinal nerve fiber layer and optic disc. It is indicated for producing high-resolution, widefield, en face reflectance images, autofluorescence images, and axial, cross-sectional images of the posterior ocular structures.	The Spectral OCT/SLO is a non-contact, high-resolution non-invasive tomographic and confocal imaging device. It is indicated for in vivo viewing, axial cross-sectional, and three-dimensional imaging and measurement of posterior ocular structures including: retina, macula, retina nerve fibre layer and optic disk. It is used as a diagnostic device to aid in the detection and management of ocular diseases affecting the posterior segment of the eye. In addition, cornea, sclera and conjunctiva can be imaged with the system by changing the focal position.	The P200DTx scanning laser ophthalmoscope is indicated for use as a widefield and retinal fluorescence and autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases and disorders that manifest in the retina. It is also indicated for use as a widefield scanning laser ophthalmoscope for viewing choroidal circulation patterns that are illuminated using Indocyanine Green dye and for aiding in both the assessment of choroidal circulation and in the diagnosis of choroiditis or choroidal diseases.
Product Code	HLI, OBO	OBO	MYC
Regulation Number	21 CFR 886.1570	21 CFR 886.1570	21 CFR 886.1570

Device Classification	II	II	II
Components	Scan head Headrest and chinrest Powered Table (separate) Computer	Scan head Headrest and chinrest Powered Table Computer	Scanhead Headrest and chinrest Powered Table (separate) Computer
Compliance Standards	ANSI/AAMI ES60601-1, -1-2, ISO 15004-2, IEC 60825-1	IEC 60601-1, -1-2, ISO 10993	IEC 60601-1, -1-2, ISO 10993, ISO 15004-2, IEC 60825
SLO Technology Characteristics			
Light Source	Laser	N/A	Laser
Wavelength and Color of Light	532nm: green 635nm: red	N/A	488nm: blue 532nm: green 635nm: red 802nm: infra-red
Laser Class	Class 1 to ISO 60825	N/A	Class 1 to ISO 60825
Number of lasers used per Scan	1 or 2	N/A	1 or 2
External Field of View	120°	N/A	120°
Internal Field of View	200°	N/A	200°
Wide Angle Digitized Image Size	3900x3072 pixels	N/A	3900x3072 pixels
Scan Patterns	2 axis scanner	N/A	2 axis scanner
Software	Embedded and Application	N/A	Embedded and Application
OCT Technology Characteristics			
Method of Operation	SD-OCT (Low coherence interferometry with fixed source)	SD-OCT (Low coherence interferometry with fixed source)	N/A
Light Source	SLD 830nm Super Luminescent Diode 782nm: infra-red	SLD 830nm Super Luminescent Diode 782nm: infra-red	N/A
Scan Rate	70,000 A-scans/s	up to 27,000 A-scan/s	N/A
Scanner Type	Galvanometric mirror pair	Galvanometric mirror pair	N/A
Light Source Classification	Class 1	Class 1	N/A
Optical Power	≤ 750µW at Cornea	≤ 750µW at Cornea	N/A
Lateral Resolution	20µm	20µm	N/A
Axial Resolution	< 10µm	< 10µm	N/A
Field of View	12mm x 9mm (40 degrees x 30 degrees)	9mm x 9mm (30 degrees x 30 degrees)	N/A
Scan Patterns	Line Scan Raster Scan Retina Topography Scan Optic Nerve Head Topography Scan	Line Scan Raster Scan Retina Topography Scan Optic Nerve Head Topography Scan	N/A

	Optic Nerve Head RNFL Ring Scan	Optic Nerve Head RNFL Ring Scan Radial Scan	
Quantitative parameters	None	Retinal thickness analysis Nerve Fibre thickness analysis Optic Nerve Head analysis	N/A
Depth Range (in air)	2.5mm	1.7 -2.3mm	N/A
Scan Pixels	Axial (depth) 1024 Lateral 1024	Axial (depth) 1024 Lateral 1024	N/A
Acquisition time	≤2s	≤2s	N/A
Retinal Tracking	Yes	Yes	N/A
General			
Ergonomics	Tabletop Scanner Headrest and Chinrest Touchscreen & Hand controller	Tabletop Scanner Headrest and Chinrest Computer	Tabletop Scanner Headrest and Chinrest Touchscreen & Hand controller
Cleaning and disinfection/ sterilization	Sterilization not required. Clean/disinfect contact points	Sterilization not required. Clean/disinfect contact points	Sterilization not required. Clean/disinfect contact points
Safety Features	Laser & SLD shutdown on light source overpower and/or incorrect functioning of scanning elements	SLD shutdown on light source overpower and/or incorrect functioning of scanning elements	Laser shutdown on laser overpower and/or incorrect functioning of scanning elements
Software	Embedded and Application	Embedded and Application	Embedded and Application
Operating System	Linux (SLO) Windows 7 (Application & OCT)	Windows XP (Application and OCT)	Linux

The optical coherence tomographer features of the P200TE are similar to the primary predicate Spectral OCT/SLO but there are minor differences. Importantly, the light sources in both devices are identical. The Spectral OCT/SLO can produce 27,000 A-scans/s while the P200TE is capable of 70,000 A-scans/s due to a change in software. The change in software also removes the ability to provide numerical measurements from the machine. The field of view difference 9mm x 9mm vs. 12mm x 9mm is minor and due to the software change. The difference in depth range 1.7 to 2.3mm vs. 2.5mm is due to the change in software.

The scanning laser ophthalmoscope features of the P200TE are similar to the secondary predicate Optos P200DTx but there are minor differences. The P200TE has removed the functionality of the Fluorescein Angiography and ICG which used a 488nm blue light source and 802nm infra-red light source in the predicate device. The P200TE can still provide Red/Green Reflectance and Auto Fluorescence. Field of view and other characteristics are all the same.

Performance data was provided which showed that the P200TE complied with recognized consensus standards as did the predicate devices. The P200TE and the predicate devices are substantially equivalent.

PERFORMANCE DATA

Non-Clinical

In addition to electrical safety and software testing performed on the device, the following bench performance testing was conducted in order to support substantial equivalence:

- ISO 15004-2:2007 Ophthalmic Instruments – Fundamental requirements and test methods – Part 2: Light hazard protection
- IEC 60825-1 Safety of Laser Products;
- IEC 62366: Application of usability engineering to medical devices.

Results of the bench testing demonstrated that the Optos P200TE complies with the relevant recognized consensus standards.

Clinical

A prospective, observational study at a single US clinical site was conducted. 35 participants age 18 or older were enrolled and assigned to one of three sub-groups, "normal" (no ocular pathology), "glaucoma," (with existing diagnosis of glaucoma of various severities), or "retinal disease" (those with a variety of retinal conditions, including, but not limited to, age-related macular degeneration, diabetic retinopathy, diabetic macular edema, macular hole, epiretinal membrane). 32 study eyes were imaged with the P200TE device and the Spectral OCT/SLO device in a randomized order. The scan patterns used were Line Scan, RNFL scan, ONH Topography, Retina Topography, and Raster scan. Images were reviewed for various imaging artifacts. Images were then compiled and submitted to a third-party reading center (outside of the US) where three independent, masked graders qualitatively evaluated the images based on pre-specified grading criteria. These criteria were based on the presence or absence of clinically relevant structures and anatomic boundaries and on the overall image clarity necessary for qualitative clinical use. Grading results from the two devices were then compared using one-tailed Wilcoxon signed-rank test analyses for a non-inferiority hypothesis and linearly weighted Cohen's kappa analyses. The grading results were found to be similar between the two devices. The kappa analyses show adequate inter-grader agreement in scoring. These results showed that the image quality for purposes of qualitative clinical use are similar between the P200TE and the Spectral OCT/SLO, and support a determination of substantial equivalence.

CONCLUSIONS

The Optos P200TE has the same intended use and indications for use, technological characteristics, and principles of operation as the previously cleared predicates. The minor differences between the subject device and the predicate devices do not raise new questions of safety or effectiveness. Therefore, the Optos P200TE is substantially equivalent to the Spectral OCT/SLO