July 31, 2019

Optos Plc
Ms. Rachel Reay
Regulatory Specialist
Queensferry House, Carnegie Campus, Enterprise Way
Dunfermline, KY11 8GR GB

Re: K190732
Trade/Device Name: P200TxE
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO, MYC
Dated: June 18, 2019
Received: June 19, 2019

Dear Ms. Reay:

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,

for Bradley Cunningham, MSE, RAC
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

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)*
K190732

Device Name P200TxE

Indications for Use *(Describe)*

The P200TxE is a non-contact scanning laser ophthalmoscope and optical coherence tomographer intended for in-vivo digital imaging of posterior ocular structures, including the vitro-retinal interface, retina, retinal layers, optic disc, choroid and choroido-scleral interface. It is indicated for producing high-resolution, wide field, en-face reflectance images, auto fluorescence images, fluorescein angiography images, indocyanine green angiography images, and axial cross-sectional images of the posterior ocular structures.

The system enables practitioners to capture multi-modal images in support of detection, investigation and monitoring of retinal conditions.

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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K190732

510(k) SUMMARY

Optos Plc's P200TxE

Optos Plc
Queensferry House
Carnegie Campus
Enterprise Way,
Dunfermline, Scotland, UK
KY11 8GR

Phone: 0044 1383 843300
Facsimile: 0044 1383 843333

Contact Person: Rachel Reay, Regulatory Specialist (rreay@optos.com)

Date Prepared: 20th March 2019

Name of Device	**P200TxE**
Common or Usual Name	**Optical Coherence Tomographer and Scanning Laser Ophthalmoscope**
Classification Name	**Scanning laser ophthalmoscope (21 CFR §866.1570)**
Regulatory Class	**Class II**
Product Code	**OBO/MYC**
Predicate Devices	**Primary: P200TE 'Monaco' (Optos Plc K173707)** **Secondary: P200DTx 'California' (Optos Plc K142897)**

Device Description

P200TxE is a desktop retinal imaging device that can perform ultra-widefield scanning laser ophthalmoscopy and targeted navigated optical coherence tomography. The device is intended to be used by ophthalmic and optometry health care professionals, most commonly in a hospital environment.

The P200TxE delivers images in the following image modes:

- Scanning Laser Ophthalmoscopy
  - Red and green reflectance
  - Green-pumped autofluorescence
  - Fluorescein Angiography
  - Indo-Cyanine Green Angiography
- Optical Coherence Tomography

The P200TxE 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 P200TxE instrument uses green laser illumination to excite autofluorescence (AF) emission from the naturally occurring lipofuscin in the human fundus.

The P200TxE 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 P200TxE instrument uses infrared swept-source laser illumination for optical coherence tomography allowing a depth profile of the reflectance of the human fundus to be recorded.

The P200TxE instrument uses blue laser illumination to excite emission from Sodium Fluorescein dye which is injected into the patient's bloodstream in a separate medical procedure as part of a Fluorescein angiography (FA) examination.

The P200TxE instrument uses Infra-red (IR) laser illumination to excite emission from Indocyanine Green dye which is injected into the patient's bloodstream in a separate medical procedure as part of an Indocyanine Green angiography (ICG) examination.

Images can be reviewed through OptosAdvance review software (K162039) either on the image server, or on individual review stations, or other DICOM compliant PACS viewers.

Intended Use / Indications for Use, P200TxE

The P200TxE is a non-contact scanning laser ophthalmoscope and optical coherence tomographer intended for in-vivo digital imaging of posterior ocular structures, including the vitro-retinal interface, retina, retinal layers, optic disc, choroid and choroido-scleral interface. It is indicated for producing high-resolution, wide field, en-face reflectance images, auto fluorescence images, fluorescein angiography images, indocyanine green angiography images, and axial cross-sectional images of the posterior ocular structures.

The system enables practitioners to capture multi-modal images in support of detection, investigation and monitoring of retinal conditions.

Summary of Technological Characteristics

The P200TxE, like the P200TE and P200DTx, 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 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.

The P200TxE refers to the scanhead component of the system, together with touchscreen and hand controller. It is supported by an image server, which delivers patient management and image storage, as well as interfacing with the business systems and hospital Electronic Medical Record systems. 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 remotely or 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.

Technological implementation of Fluorescein Angiography and Indocyanine Green Angiography imaging is identical between P200TxE and P200DTx.

P200TxE incorporates a swept-source light source to divide wavelengths temporally, while the P200TE incorporates a superluminescent diode (SLD) light source and a splitter to divide wavelengths spatially. Though the methods used to divide wavelengths are different, both are based on optical interference principles, and both spectral domain and swept-source OCT are generally thought to fall under the umbrella classification of Fourier Domain OCT.

OCT safety and effectiveness has been demonstrated through bench and clinical testing.

Substantial Equivalence to predicate devices

Both P200TxE and P200TE are non-contact scanning laser ophthalmoscope and optical coherence tomographers intended for in-vivo digital imaging of posterior ocular structures.

In other words, the P200TxE has the same intended use its predicate device. Thus, the P200TxE satisfies the first criterion for a finding of substantial equivalence.

The P200TxE has all the same indications for use as P200TE. Additionally it includes FA and ICG fluorescence angiography imaging functionality, present in the second predicate device, P200DTx.

With the exception of the upgrade to the OCT engine described above, P200TxE contains all the operational components of both the P200TE and P200DTx.

All three devices are operated by touchscreen and hand controller. GUIs are presented to the user with branding and presentation styles consistent across the Optos range of devices.

A table comparing the key features of the subject and predicate devices is provided below:

510(k) Summary Substantial Equivalence Chart

Device	OPTOS P200TxE	OPTOS P200TE	OPTOS P200DTx
510(k) Number	**---**	**K173707**	**K142897**
Indications For Use	The P200TxE is a non-contact scanning laser ophthalmoscope and optical coherence tomographer intended for in-vivo digital imaging of posterior ocular structures, including the vitro-retinal interface, retina, retinal layers, optic disc, choroid and choroido-scleral interface. It is indicated for producing high-resolution, wide field, en-face reflectance images, auto fluorescence images, fluorescein angiography images, indocyanine green angiography images, and axial cross-sectional images of the posterior ocular structures. The system enables practitioners to capture multi-modal images in support of detection, investigation and monitoring of retinal conditions.	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 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	MYC, OBO	MYC, OBO	MYC
Regulation Number	21 CFR 886.1570	21 CFR 886.1570	21 CFR 886.1570
Device Classification	II	II	II
Components	Scanhead Headrest and chinrest Powered Table (separate) Computer	Scanhead Headrest and chinrest Powered Table (separate) Computer	Scanhead Headrest and chinrest Powered Table (separate) Computer
SLO Technology characteristics			
Light Source	Laser	Laser	Laser
Wavelength and Color of Light	488nm: blue 532nm: green 635nm: red 802nm: infra-red	532nm: green 635nm: red	488nm: blue 532nm: green 635nm: red 802nm: infra-red
Laser Class	Class 1 to ISO 60825	Class 1 to ISO 60825	Class 1 to ISO 60825
Number of lasers used per Scan	1 or 2	1 or 2	1 or 2
External Field of View	120°	120°	120°
Internal Field of View	200°	200°	200°

Wide Angle Digitized Image Size	3900x3072 pixels	3900x3072 pixels	3900x3072 pixels
Scan Patterns	2 axis scanner	2 axis scanner	2 axis scanner
Software	Embedded and Application	Embedded and Application	Embedded and Application
OCT Technology characteristics			
Method of Operation	SS-OCT (Low coherence interferometry with wavelength sweeping source)	SD-OCT (Low coherence interferometry with fixed source)	
Light Source	Swept source laser Centre wavelength 1050 +/- 10 nm With wavelength sweep range – 100 nm Tracking 802 nm laser	SLD 830nm Super Luminescent Diode SLD 828 to 837nm centre wavelength with >15nm FHWM bandwidth 782nm ±3nm: infra-red	N/A
Scan Rate	100,000 A-scans/s	70,000 A-scans/s	N/A
Scanner Type	Galvanometric mirror pair	Galvanometric mirror pair	N/A
Light Source Classification	Class 1	Class 1	N/A
Lateral Resolution	20µm	20µm	N/A
Axial Resolution	< 7µm	< 10µm	N/A
Field of View	48 degrees x 30 degrees 20 x 20 Navigated (degrees within UWF addressable image) 80 degree Extended OCT Line	40 degrees x 30 degrees	N/A
Scan Patterns	Line Volume	Line Volume Circle	N/A
Depth Range (in air)	>3.5mm	2.5mm	N/A
Acquisition time	≤3s	≤2s	N/A
Retinal Tracking	Yes	Yes	N/A
General			
Ergonomics	Tabletop Scanner Headrest and Chinrest Touchscreen & Hand controller	Tabletop Scanner Headrest and Chinrest Touchscreen & Hand controller	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 & SweptSource shutdown on light source overpower and/or incorrect functioning of scanning elements	Laser & 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)	Linux (SLO); Windows 7 (Application & OCT)	Linux

Performance Data

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 P200TxE complies with the relevant recognized consensus standards.

Clinical Data

A Comparative Qualitative OCT Image Grading Study was conducted between the Optos P200TxE and the Optos P200TE. The clinical utility and quality of OCT B scans from the P200TxE device (investigational device) were found to be very similar to the B scans from the P200TE device (predicate device). The visualization of pathology in the B scans of retina patients was also found to be very similar. A one-tailed non-parametric test found the P200TxE images were non-inferior to the predicate images. The average grading result across all three graders found the P200TxE images were graded higher than the predicate images for all questions about the clinical utility of retinal structures, the overall image quality, and the visualization of pathologic changes. A Kappa analysis shows the graders had reasonably good agreement in their results, and all three graders had similar trends in their scoring. These results provide compelling evidence that the B scans from the investigational device are substantially equivalent to the images from the predicate device in terms of clinical utility, image quality, and visualization of pathology.

Conclusions

The P200TxE and P200TE have the same intended use and similar indications, technological characteristics and principles of operation. Additionally P200TxE incorporates the intended use and indications for use of P200DTx. The only technological differences between the P200TxE and its predicates are associated with the:

(1) Upgrade of OCT engine from Spectral Domain to Swept Source;

(2) Navigated OCT capture within the addressable UWF image (visualization only).

These differences do not present different questions of safety or effectiveness than the predicate device because there are no novel technological principles or applications introduced and in both cases functionality can be demonstrated through bench and clinical testing. They do not alter the intended use of the device as an aid to diagnosis. Thus, the P200TxE is substantially equivalent to the P200TE and P200DTx.