August 18, 2023

Optos Plc
Rachel Reay
Senior Regulatory Affairs Specialist
Queensferry House, Carnegie Campus
Enterprise Way
Dunfermline, Fife KY11 8GR
United Kingdom

Re: K231673
Trade/Device Name: P200te (a10700)
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO
Dated: June 7, 2023
Received: June 8, 2023

Dear Rachel 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,

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

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.

Submission Number *(if known)*

K231673

Device Name

P200TE (A10700)

Indications for Use *(Describe)*

The P200TE is a non-contact scanning laser ophthalmoscope and optical coherence tomographer. It is intended for in-vivo viewing, digital imaging, and analysis of posterior ocular structures, including the retina, retinal nerve fiber layer, ganglion cell complex (GCC) and optic disc, under mydriatic and non-mydriatic conditions.

It is indicated for producing high resolution, ultra-widefield, en face reflectance images, autofluorescence images, axial cross-sectional images, three-dimensional images, retinal layer boundary analysis, optic nerve head analysis and thickness maps.

The P200TE is indicated for use as a device to aid in the detection, diagnosis, documentation and management of retinal health and diseases that manifest in the retina.

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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510(k) Summary

1. Contact Details

Applicant	Optos Plc Queensferry House Carnegie Campus Enterprise Way Dunfermline, Fife Scotland, UK KY11 8GR
Primary Correspondent	Rachel Reay Sr. Regulatory Affairs Specialist, Optos Plc Tel: 0044 1383 843300 E-mail: RA@optos.com (preferred)
Date Prepared	**July 24th 2023**

2. Subject Device

Device Trade Name	P200TE (A10700)
Common Name	Ophthalmoscope
Classification	Tomography, Optical Coherence
Regulatory Class	886.1570
Product Code	OBO

3. Legally Marketed Predicate Devices

Predicate #	K173707	K121739
Device Trade Name	P200TE (A10700)	iVue
Product Code	OBO	OBO

4. Device Description

P200TE is a desktop retinal imaging device that can perform ultra-widefield scanning laser ophthalmoscopy and optical coherence tomography. Ultra-widefield images can be captured in less than half a second. The device is intended to be used by ophthalmic and optometry health care professionals.

The P200TE delivers images in the following image modes:

- Scanning Laser Ophthalmoscopy
- Reflectance imaging
- Autofluorescence imaging
- Optical Coherence Tomography

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 fundus.

The P200TE instrument uses a broadband near-infrared (N-IR) super-luminescent diode (SLD) light source for optical coherence tomography allowing a depth profile of the reflectance of the fundus to be recorded. The P200TE instrument uses N-IR laser illumination for reflectance imaging simultaneously with OCT imaging. Reflectance images are used to track eye position during OCT imaging and are not available to the user.

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.

P200TE OCT images are automatically segmented to identify and annotate retinal layers and structures, enabling practitioners to efficiently assess retinal structures in support of detecting, monitoring and documentation. Segmentation outcomes are recorded as annotations and support adjustment as deemed necessary by the clinician.

P200TE automatic segmentation provides comprehensive retinal and optic nerve head information, including:

- Full Retinal Thickness (FRT)
- Ganglion Cell Complex Thickness (GCC)
- ONH Cup and Disc Analysis
- ONH Nerve Fiber Layer Thickness

The P200TE refers to the scan head component of the system, together with touchscreen and hand controller. The device is supported by an image server which delivers patient management and image storage, as well as interfacing with the business systems and 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 PCs 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.

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

5. Indications for Use

The P200TE is a non- contact scanning laser ophthalmoscope and optical coherence tomographer. It is intended for in-vivo viewing, digital imaging, and measurement of posterior ocular structures, including the retina, retinal nerve fiber layer, ganglion cell complex (GCC) and optic disc under mydriatic and non-mydriatic conditions.

It is indicated for producing high resolution, ultra- widefield, en face reflectance images, autofluorescence images, axial cross-sectional images, three-dimensional images, retinal layer boundary analysis, optic nerve head analysis and thickness maps.

The P200TE is indicated for use as a device to aid in the detection, diagnosis, documentation and management of retinal health and diseases that manifest in the retina.

6. Substantial Equivalence to Predicate

The updated P200TE has all the same indications for use as P200TE and alongside this introduces the capability to produce retinal layer boundary analysis, optic nerve head analysis and thickness maps, present in the second predicate device, iVue. In other words, the P200TE has the same intended use its predicate devices, and thus satisfies the first criterion for a finding of substantial equivalence.

Both P200TE and iVue are Spectral Domain optical coherence tomographers intended for in- vivo digital imaging and measurement of posterior ocular structures, with retinal layer boundary analysis, optic nerve head analysis and thickness maps.

Technological implementation of SLO and OCT imaging is identical between the cleared P200TE and the submitted P200TE with segmentation. Both the current and updated 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.

Technological implementation of OCT imaging in the iVue is comparable to the P200TE in that both systems operate via a superluminescent diode (SLD) light source of equivalent wavelengths and a splitter to divide wavelengths spatially, based on optical interference principles and under the umbrella classification of Fourier Domain OCT.

P200TE with segmentation is substantially equivalent to the previously cleared P200TE, and segmentation functionality is also substantially equivalent to the Optovue iVue. Minor differences in segmentation implementation do not present different questions of safety or effectiveness than the predicate device because there are no novel technological principles or applications introduced.

Table 1: Substantial Equivalence Chart

Device	**OPTOS P200TE with segmentation**	**OPTOS P200TE**	**Optovue iVue**
510(k) Number	**---**	**K173707**	**K121739**
Indications For Use	The P200TE is a non-contact scanning laser ophthalmoscope and optical coherence tomographer. It is intended for in-vivo viewing, digital imaging, and analysis of posterior ocular structures, including the retina, retinal nerve fiber layer, ganglion cell complex (GCC) and optic disc, under mydriatic and non-mydriatic conditions. It is indicated for producing high resolution, ultra-widefield, en face reflectance images, autofluorescence images, axial cross-sectional images, three-dimensional images, retinal layer boundary analysis, optic nerve head analysis and thickness maps. The P200TE is indicated for use as a device to aid in the detection, diagnosis, documentation and management of retinal health and diseases that manifest in the retina.	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 iVue is a non-contact, high resolution tomographic imaging device. It is intended for in vivo imaging, axial cross-sectional, and three-dimensional imaging and measurement of anterior and posterior ocular structures, including retina, retinal nerve fiber layer, ganglion cell complex (GCC), optic disc, cornea, and anterior chamber of the eye. The iVue with Normative Database is a quantitative tool for the comparison of retina, retinal nerve fiber layer, ganglion cell complex, and optic disc measurements to a database of known normal subjects. The iVue with Normative Database is indicated for use as a device to aid in the diagnosis, documentation, and management of ocular health and diseases in the adult population.
Product Code	MYC, OBO	MYC, OBO	HLI, OBO
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	Scanner Computer Control box Footswitch (optional) Joystick and chinrest assembly
SLO Technology characteristics			
Light Source	Laser	Laser	N/A
Wavelength and Color of Light	532nm ±5nm: green 635nm ±5nm: red	532nm ±5nm: green 635nm ±5nm: red	N/A
Laser Class	Class 1 to ISO 60825	Class 1 to ISO 60825	N/A
Number of lasers used per Scan	1 or 2	1 or 2	N/A
External Field of View	120°	120°	N/A
Internal Field of View	200°	200°	N/A
Wide Angle Digitized Image Size	3900x3072 pixels	3900x3072 pixels	N/A
Scan Patterns	2 axis scanner	2 axis scanner	N/A
Software	Embedded and Application	Embedded and Application	N/A
OCT Technology characteristics			
Method of Operation	Spectral Domain OCT	Spectral Domain OCT	Spectral Domain OCT
Light Source	SLD 830-850nm Super Luminescent Diode Nominal center wavelength 840nm 50nm FHWM bandwidth 782nm ±3nm: infra-red	SLD 830nm Super Luminescent Diode SLD 828 to 837nm center wavelength with >15nm FHWM bandwidth 782nm ±3nm: infra-red	SLD 830 nm to 850 nm Super Luminescent Diode
Scan Rate	70,000 A-scans/s	70,000 A-scans/s	25,000 A-Scans/s
Scanner Type	Galvanometric mirror pair	Galvanometric mirror pair	Lens based system
Light Source Classification	Class 1	Class 1	Class 1
Transverse Resolution	20µm	20µm	15µm
Axial Resolution	< 7µm	< 10µm	5µm
Transverse scan range	5.28 mm to 12 mm	6 mm to 12 mm	2 mm to 12 mm
Scan Patterns	Line Volume Circle	Line Volume Circle	Line Volume Circle

Depth Range (in tissue)	2.3mm	2.3mm	2.3mm
Acquisition time	≤2s	≤2s	≤2s
Retinal Tracking	Yes	Yes	No
Ergonomics	Tabletop Scanner Headrest and Chinrest Touchscreen & Hand controller	Tabletop Scanner Headrest and Chinrest Touchscreen & Hand controller	Tabletop Scanner Computer Control box Footswitch (optional) Joystick and chinrest assembly
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	Laser & SLD shutdown on light source overpower and/or incorrect functioning of scanning elements	Halt to operation for status abnormality
Software	Embedded and Application	Embedded and Application	Embedded and Application
Operating System	Linux (SLO) Windows (Application & OCT)	Linux (SLO) Windows (Application & OCT)	32 or 64 bit Windows XP Pro. Ed./Win 7
OCT Analysis			
Retinal Thickness			
Full Retinal Thickness	9 sector ETDRS	N/A	9 sector ETDRS
GCC Thickness	Averaged; Fovea-centered Hemifields	N/A	Averaged; Temporally Offset Hemifields
Optic Disc Analysis			
RNFL peripapillary	Averaged, Quads, TSNIT	N/A	Averaged, quads, TSNIT
Disc area	Yes	N/A	Yes
Rim area	Yes – reference plane model	N/A	Yes – fixed offset model
C/D area	Yes	N/A	Yes
C/D horizontal ratio	Yes	N/A	Yes
C/D vertical ratio	Yes	N/A	Yes

Table 2: The physical principles of operation for each modality, consistent with the predicate device P200TE

Modality	Imaging mode	Physical principle	Output	Use scenario
Reflectance imaging (SLO)	Optomap UWF composite Red / Green retinal imaging Optomap/Optomap plus resolution modes	Point by point mapping of reflected light intensity from multi-channel laser incident on retina.	2D image of the retina.	To enable UWF visualization and quantitative assessment of the retina, choroid, optic nerve head and nerve fiber layer when viewed in a compatible DICOM viewer.
Fluorescence imaging (SLO)	Optomap UWF Auto-Fluorescence (AF) imaging Optomap/Optomap plus resolution modes	Point by point mapping of fluorescence light intensity from multi-channel laser incident on retina.	2D image of the retina. AF relies on natural fluorophores present in retina.	To enable UWF visualization and quantitative assessment of the health of the cells when viewed in a compatible DICOM viewer. Areas of Hypo and Hyper fluorescence are used by practitioners to assess the metabolism of the eye.
Optical Coherence Tomography (OCT)	Central Posterior OCT Imaging	Point by point mapping of back-scattered light intensity, resolved in the axial direction through coherence gating. Coherence gating is achieved through low-coherence interferometry. Low coherence light is incident on the retina for axial mapping.	2D axial cross section (B-scan) or 3D volume (C-scan) of retina. Provides structural information of retina in the axial and transverse direction	To support investigation of anomalies found in the SLO RG or AF, and to broadly assess the health at the Macula and through the ONH. Providing 3D structural information in the macular and ONH regions, through single scans or a combination of scans. For use in conjunction with Red-Green and Auto Fluorescence SLO images to assess eye health

7. Summary of Studies

Non-Clinical Performance Testing

Non-clinical system testing provided an evaluation of the performance of the system relevant to each of the system specifications. The functional and system level testing showed that the system met the defined specifications, with no concerns raised in relation to key non-functional performance parameters.

Design Verification of the A10700 P200TE including the following Non-functional performance parameters recommended for all OCT devices, in line with FDA's OCT Pilot Guidance document:

- Spatial performance testing (Lateral range; Lateral resolution; Axial range; Axial resolution)
- Sensitivity (Signal-to-Noise ratio, depth attenuation)
- Auxiliary Functions

The P200TE is type tested in accordance with the following standards:

- IEC 60601-1:2015+A11:2021 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+A1:2020 Medical electrical equipment – Part 1.2: General requirements for safety – collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 60825-1:2007 Safety of laser products - Part 1: Equipment classification and requirements

Safety Calculations are also provided with reference to ANSI Z80.36-2021 Ophthalmics - Light Hazard Protection for Ophthalmic Instruments.

Sterility, Shelf-Life, Biocompatibility and Animal Testing was not required for this submission.

Software verification and validation has been conducted in accordance with QMS processes and documentation has been provided with this submission.

All testing has passed with no additional safety or performance concerns raised.

Clinical Performance Testing

This was a prospective, single site study. A total of 106 subjects were enrolled: with 35 subjects without ovular pathology, 35 with glaucoma, and 35 with retina pathology. One subject was withdrawn because they did not meet the inclusion/exclusion criteria. Mean age for all subjects was 46.8 years with a range from 22 to 75 years of age. Mean age for the normal group was 36 years with a range from 23 to 59 years of age, mean age for the glaucoma group was 61.7 years with a range from 37 to 75, and mean age of the retina group was 42.4 with a range from 22 to 74. There were 44 male subjects (41.5%) and 62 female subjects (58.5%). There were 12 Asian subjects (11.3%), 39 White subjects (36.8%), and 54 Black subjects (50.9%) with 1 other (0.9%). For the P200TE, 85.6 % of scans were acceptable, and for the iVue, 94.0% of scans were acceptable. The most common reasons for scans not being acceptable included eye blinks, eye movements, low signal strength, clipping, and poor centration.

The study design was a 3 x 3 crossed study with 3 P200TE devices and 3 iVue predicate devices with 3 operators assigned to image on a fixed pair of P200TE and iVue devices. Three acceptable scans of each scan type were acquired on each of the study devices. Analysis of variance was performed to determine the repeatability and reproducibility as well as the variance associated with the combination of operator and device. Agreement between the P200TE and iVue was evaluated with a Bland Altman analysis and Deming Regression analysis.

Agreement and precision analysis was performed on all measurement parameters for Full Retina Thickness (FRT), Retinal Nerve Fiber Layer (RNFL) thickness, Ganglion Cell Complex (GCC) thickness, and Optic Nerve Head (ONH) measurements.

This study found excellent agreement and precision of the Optos P200TE compared to the Optovue iVue. The performance goals for agreement were met for all FRT, RNFL, and ONH parameters for all groups. Because the iVue GCC grid is shifted 1 mm temporally from the fovea, it is in a more peripheral region where the layer is thinner, therefore the agreement performance goals were not met for GCC, due to the difference in scan location.

For precision, performance goals were met for all parameters and all groups. When directly comparing coefficient of variation calculations, the P200TE had lower variability than the iVue in 96% of the parameters for repeatability and 94% of the parameters for reproducibility.

Precision Details

Table 3 Summary of Repeatability and Reproducibility for Full Retinal Thickness (FRT) for Optos P200TE

		Repeatability			Reproducibility		
	Overall Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Device: P200TE							
Parameter: Normal: N = 35							
Fovea Thickness (µm)	245.4708	2.2433	6.2813 (1.1660)	0.91%	2.7779	7.7782 (1.0573)	1.13%
Superior Inner (µm)	317.3858	1.6796	4.7028 (0.6021)	0.53%	2.0305	5.6855 (0.5618)	0.64%
Temporal Inner (µm)	304.2953	1.7876	5.0053 (0.7547)	0.59%	2.0236	5.6660 (0.6153)	0.66%
Inferior Inner (µm)	314.8044	1.6508	4.6223 (0.6242)	0.52%	1.8993	5.3179 (0.5401)	0.60%
Nasal Inner (µm)	318.5472	1.9892	5.5698 (0.7057)	0.62%	2.318	6.4903 (0.5800)	0.73%
Superior Outer (µm)	278.9673	1.2313	3.4476 (0.5243)	0.44%	1.7878	5.0058 (0.5467)	0.64%
Temporal Outer (µm)	259.5717	1.2305	3.4454 (0.5375)	0.47%	1.6091	4.5055 (0.5728)	0.62%
Inferior Outer (µm)	266.6306	1.1131	3.1166 (0.5191)	0.42%	1.1957	3.3480 (0.4207)	0.45%
Nasal Outer (µm)	294.5348	1.1008	3.0822 (0.5624)	0.37%	1.3478	3.7738 (0.5173)	0.46%
Device: P200TE							
Parameter: Glaucoma: N = 35							
Fovea Thickness (µm)	228.5799	2.2461	6.2889 (0.9031)	0.98%	3.0542	8.5518 (0.9603)	1.34%
Superior Inner (µm)	288.5327	1.8753	5.2509 (0.6844)	0.65%	2.2643	6.3401 (0.6051)	0.78%
Temporal Inner (µm)	275.6294	1.4952	4.1867 (0.5483)	0.54%	2.089	5.8491 (0.5933)	0.76%
Inferior Inner (µm)	281.5857	1.5804	4.4251 (0.6852)	0.56%	1.9364	5.4219 (0.5649)	0.69%
Nasal Inner (µm)	292.4215	1.8424	5.1587 (0.7236)	0.63%	2.3546	6.5928 (0.6083)	0.81%
Superior Outer (µm)	251.375	1.467	4.1077 (0.6151)	0.58%	2.1399	5.9916 (0.6439)	0.85%
Temporal Outer (µm)	238.2408	1.2304	3.4451 (0.5954)	0.52%	1.5154	4.2432 (0.5437)	0.64%
Inferior Outer (µm)	235.0803	1.5295	4.2826 (0.6384)	0.65%	1.7507	4.9020 (0.6040)	0.74%
Nasal Outer (µm)	264.0763	1.292	3.6176 (0.6870)	0.49%	1.6679	4.6701 (0.6651)	0.63%
Device: P200TE							
Parameter: Retinal Disease: N = 35							
Fovea Thickness (µm)	245.9433	2.313	6.4763 (0.9118)	0.94%	2.7517	7.7047 (0.8704)	1.12%
Superior Inner (µm)	311.8596	2.0411	5.7151 (0.6354)	0.65%	2.402	6.7257 (0.5319)	0.77%
Temporal Inner (µm)	300.1217	1.6941	4.7435 (0.5355)	0.56%	2.0316	5.6885 (0.4459)	0.68%
Inferior Inner (µm)	305.6997	1.6879	4.7260 (0.6365)	0.55%	1.8264	5.1138 (0.4837)	0.60%
Nasal Inner (µm)	310.089	2.1686	6.0721 (0.6474)	0.70%	2.5049	7.0138 (0.5858)	0.81%
Superior Outer (µm)	278.7518	1.7344	4.8564 (0.7350)	0.62%	2.4046	6.7330 (0.7199)	0.86%
Temporal Outer (µm)	258.385	1.4445	4.0446 (0.6087)	0.56%	1.9443	5.4441 (0.6241)	0.75%
Inferior Outer (µm)	262.6416	1.3213	3.6997 (0.5266)	0.50%	1.6081	4.5028 (0.5164)	0.61%
Nasal Outer (µm)	287.4438	1.1278	3.1579 (0.4773)	0.39%	1.3735	3.8459 (0.4738)	0.48%

Table 4 Summary of Repeatability and Reproducibility for Retinal Nerve Fiber Layer (RNFL) Averaged Thickness for Optos P200TE

		Repeatability			Reproducibility		
	Overall Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Device: P200TE Parameter: Normal: N = 35							
Temporal (µm)	87.8741	2.193	6.1404 (0.8004)	2.50%	2.8603	8.0090 (1.0286)	3.26%
Superior (µm)	129.4382	2.9074	8.1408 (0.8801)	2.25%	3.8931	10.9007 (1.0362)	3.01%
Inferior (µm)	138.4245	3.0448	8.5253 (0.8551)	2.20%	3.5419	9.9174 (0.8626)	2.56%
Nasal (µm)	82.417	2.3247	6.5091 (0.9594)	2.82%	2.6403	7.3928 (0.9873)	3.20%
Average RNFL (µm)	109.532	1.2388	3.4687 (0.7844)	1.13%	1.613	4.5163 (0.8380)	1.47%
Device: P200TE Parameter: Glaucoma: N = 35							
Temporal (µm)	66.6774	1.9836	5.5540 (0.5751)	2.97%	2.4773	6.9365 (0.7074)	3.72%
Superior (µm)	93.9096	2.5423	7.1184 (1.0900)	2.71%	3.1287	8.7603 (1.1456)	3.33%
Inferior (µm)	94.4738	2.4156	6.7635 (0.8296)	2.56%	2.7131	7.5967 (0.8421)	2.87%
Nasal (µm)	71.6069	2.2444	6.2843 (0.7771)	3.13%	2.6327	7.3715 (0.9115)	3.68%
Average RNFL (µm)	81.6628	1.1553	3.2349 (0.7899)	1.41%	1.4947	4.1850 (0.9208)	1.83%
Device: P200TE Parameter: Retinal Disease: N = 35							
Temporal (µm)	86.1527	2.3445	6.5646 (0.8329)	2.72%	2.7795	7.7825 (0.9831)	3.23%
Superior (µm)	126.8979	2.8994	8.1183 (1.0058)	2.28%	3.7232	10.4251 (1.0630)	2.93%
Inferior (µm)	136.4571	3.0268	8.4750 (0.9686)	2.22%	3.3728	9.4439 (0.8796)	2.47%
Nasal (µm)	83.8697	2.4993	6.9979 (0.8994)	2.98%	2.8858	8.0804 (0.9923)	3.44%
Average RNFL (µm)	108.3317	1.3505	3.7813 (0.9465)	1.25%	1.6093	4.5060 (0.9242)	1.49%

Table 5 Summary of Repeatability and Reproducibility for GCC thickness for Optos P200TE

		Repeatability			Reproducibility		
	Overall Mean	SD	Limit (Ratio)	CV%	SD	Limit (Ratio)	CV%
Device: P200TE Parameter: Normal: N = 35							
Superior Average (µm)	108.8597	0.9591	2.6854 (1.0811)	0.88%	1.3697	3.8351 (1.2665)	1.26%
Inferior Average (µm)	111.2212	0.9649	2.7019 (0.9984)	0.87%	1.2174	3.4087 (1.0866)	1.09%
Inner Retina Average (µm)	110.0406	0.8493	2.3780 (0.9799)	0.77%	1.1677	3.2696 (1.1220)	1.06%
Device: P200TE Parameter: Glaucoma: N = 35							
Superior Average (µm)	90.5858	1.0657	2.9840 (0.8296)	1.18%	1.6234	4.5456 (1.1003)	1.79%
Inferior Average (µm)	87.2697	1.1786	3.2999 (1.0180)	1.35%	1.4879	4.1662 (1.1289)	1.70%
Inner Retina Average (µm)	88.9275	0.9498	2.6593 (0.8537)	1.07%	1.3659	3.8246 (1.0608)	1.54%
Device: P200TE Parameter: Retinal Disease: N = 35							
Superior Average (µm)	107.1894	1.3174	3.6888 (0.9058)	1.23%	1.7787	4.9805 (1.0089)	1.66%
Inferior Average (µm)	107.0354	1.1198	3.1356 (0.8096)	1.05%	1.4884	4.1674 (0.9341)	1.39%
Inner Retina Average (µm)	107.1125	0.9591	2.6856 (0.8219)	0.90%	1.3467	3.7706 (0.9607)	1.26%

Table 6 Summary of Repeatability and Reproducibility for Optic Nerve Head (ONH) Measurements for Optos P200TE

		Repeatability			Reproducibility		
	Overall Mean	SD	Limit (ratio)	CV%	SD	Limit (ratio)	CV%
Device: P200TE Parameter: Normal: N = 35							
C/D Horizontal Ratio	0.2946	0.0203	0.0567 (0.4455)	6.88%	0.0234	0.0656 (0.5128)	7.96%
C/D Vertical Ratio	0.315	0.0176	0.0492 (0.3909)	5.57%	0.0199	0.0558 (0.4347)	6.33%
C/D Area Ratio	0.1292	0.0095	0.0266 (0.5033)	7.35%	0.0113	0.0317 (0.5699)	8.75%
Disk Area (mm2)	1.7287	0.0615	0.1721 (0.5668)	3.56%	0.082	0.2297 (0.6130)	4.75%
Rim Area (mm2)	1.4957	0.0568	0.1592 (0.5424)	3.80%	0.0767	0.2146 (0.5922)	5.12%
Device: P200TE Parameter: Glaucoma: N = 35							
C/D Horizontal Ratio	0.7711	0.0229	0.0641 (0.9152)	2.97%	0.0254	0.0712 (0.9872)	3.30%
C/D Vertical Ratio	0.7942	0.0247	0.0691 (0.9424)	3.11%	0.0255	0.0714 (0.9116)	3.21%
C/D Area Ratio	0.6211	0.0235	0.0657 (0.9719)	3.78%	0.0264	0.0740 (1.0315)	4.25%
Disk Area (mm2)	2.2241	0.0632	0.1769 (0.5605)	2.84%	0.0712	0.1994 (0.5707)	3.20%
Rim Area (mm2)	0.831	0.0596	0.1670 (0.7388)	7.18%	0.0654	0.1832 (0.7656)	7.87%
Device: P200TE Parameter: Retinal Disease: N = 35							
C/D Horizontal Ratio	0.4494	0.0221	0.0618 (0.5038)	4.91%	0.0244	0.0682 (0.4848)	5.42%
C/D Vertical Ratio	0.4686	0.0214	0.0600 (0.4484)	4.58%	0.0238	0.0667 (0.4974)	5.09%
C/D Area Ratio	0.2381	0.0148	0.0414 (0.5324)	6.22%	0.0181	0.0507 (0.6515)	7.61%
Disk Area (mm2)	1.8689	0.0608	0.1701 (0.5058)	3.25%	0.0754	0.2112 (0.5528)	4.04%
Rim Area (mm2)	1.3939	0.0578	0.1618 (0.4883)	4.15%	0.075	0.2099 (0.5739)	5.38%

8. Conclusion

The existing and updated P200TE devices have the same intended use, technological characteristics and principles of operation, and similar indications. Additionally, the updated P200TE incorporates the Segmentation functionality of the iVue.

Minor differences in segmentation implementation do not present different questions of safety or effectiveness than the predicate device because there are no novel technological principles or applications introduced. Functionality has been demonstrated against statistical performance goals and comparison to the predicate. Thus, the P200TE is substantially equivalent to the stated predicates.