DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 21, 2017

Carl Zeiss Suzhou Co., Ltd.
% Dong Hua
Sr. Regulatory Affairs Specialist
Carl Zeiss Meditec, Inc.
5160 Hacienda Drive
Dublin, CA 94568

Re: K163195
Trade/Device Name: PRIMUS
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO
Dated: May 8, 2017
Received: May 9, 2017

Dear Dong Hua:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Kesia Alexander

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163195

Device Name

PRIMUS

Indications for Use *(Describe)*

The PRIMUS instrument is a non-contact, high resolution tomographic and biomicroscopic imaging device. It is indicated for in-vivo viewing of axial cross sections and measurement of posterior ocular structures, including retina, retinal nerve fiber layer, macula, and optic disc. It is intended for use 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.

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 (REVISED)

510(k) SUMMARY
(per 21 CFR §807.92)

PRIMUS

GENERAL INFORMATION

Applicant:	Carl Zeiss Suzhou Co., Ltd. Modern Industrial Square 3b No. 333 Xing Pu Road Sip Suzhou, Jiangsu 215126 China + 86-512-8227-3436 (phone) + 86-512-6287-1366 (fax) Establishment Registration Number: 3008564898
Contact Person:	Dong Hua Sr. Regulatory Affairs Specialist Carl Zeiss Meditec, Inc. 5160 Hacienda Drive Dublin, CA 94568 (925) 557-4204 Phone (925) 557-4259 Fax E-mail: dong.hua@zeiss.com
Date Prepared:	June 09, 2017
Common Name:	Tomography, Optical Coherence
Classification Name:	Ophthalmoscope
Product Code and Class:	OBO – Class II
Classification Number:	21 CFR 886.1570
Trade/Proprietary Name:	PRIMUS
Model:	200

PREDICATE DEVICE

Company:	Carl Zeiss Meditec, Inc.
Device:	Cirrus HD-OCT with Retinal Nerve Fiber Layer (RNFL), Macular, Optic Nerve Head and Ganglion Cell Normative Databases (K111157)

It is the opinion of Carl Zeiss Suzhou Company, Limited that the PRIMUS instrument is substantially equivalent to the predicate Cirrus HD-OCT with Retinal Nerve Fiber Layer (RNFL), Macular, Optic Nerve Head and Ganglion Cell Normative Databases Model 4000 (K111157) for the intended use for imaging and measurements of posterior ocular structures. The PRIMUS device is an ophthalmic diagnostic instrument that provides only the essential performance and functionality compared to Cirrus™ HD-OCT, e.g. with a separate manual-controlled patient interface and basic analysis features.

INDICATIONS FOR USE (21 CFR §807.92(a)(5))

The PRIMUS instrument is a non-contact, high resolution tomographic and biomicroscopic imaging device. It is indicated for in-vivo viewing of axial cross sections and measurement of posterior ocular structures, including retina, retinal nerve fiber layer, macula, and optic disc. It is intended for use 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.

DEVICE DESCRIPTION SUMMARY (21 CFR §807.92(a)(4))

The PRIMUS device is an ophthalmic instrument that provides the essential performance and functionality compared to the Carl Zeiss Meditec CIRRUS™ HD-OCT Model 4000 (K111157), with a separate manually-controlled patient interface and simplified analysis features. PRIMUS uses the same SD-OCT technology from the CIRRUS and offers a simplified user interface. In addition, the camera in the PRIMUS instrument operates at a reduced speed to acquire OCT images at comparable resolution in approximately the same amount of time.

Device Overview

The PRIMUS device is a computerized ophthalmologic instrument that acquires and allows visualization of cross-sectional tomograms of the eye using spectral domain optical coherence tomography (SD-OCT). The instrument is designed to scan the eye in a non-contact manner to acquire detailed cross-sectional images of various posterior ocular structures such as the retina and the optic nerve head. Various retinal structures of the eye from the internal limiting membrane to the retinal pigment epithelium (including layers such as the ganglion and retinal nerve fiber) can be imaged.

The PRIMUS instrument is available in one model, Model 200, which has a manually controlled patient interface and separate enclosure with components used in OCT scanning. The operator utilizes a keyboard, monitor and mouse to interface with the computer. Data acquired can be saved to the computer; PDFs of the reports may be saved to a USB-connected storage device.

The principle of operation is identical in that both devices employ a non-invasive, non-contact low-coherence interferometry technique [specifically, spectral domain optical coherence tomography (SD-OCT) to generate high-resolution cross-sectional images of internal ocular tissue microstructures by measuring optical reflections from tissue. Both provide cross sectional images of the posterior structures of the eye (i.e., retina, including the ganglion and retinal

nerve fiber layers).

The device consists of two main parts: a manually controlled separate patient interface and an imaging engine box. The system is composed of a number of electrical, mechanical, and optical subsystems that are required to facilitate measurements and aid in patient alignment:

- Optical head modules
- SD-OCT engine modules
- Patient module
- Support modules

As part of its report driven workflow, at the completion of scan acquisition, PRIMUS presents the pre-ordered report(s) to the user in a sequential manner. The visualization and analysis reports that available in PRIMUS are as follows:

- Macular Thickness Analysis (MTA) – Based on 512 X 32 Macular Cube Scan
- Optic Nerve Head (ONH) & Retinal Nerve Fiber Layer (RNFL) Analysis – Based on 128 X 128 ONH & RNFL Cube Scan
- HD 5-line Analysis – Based on 5 line HD Raster Scan
- HD 1-line Analysis – Based on 1 line HD Raster Scan

Description of Software

Software version 2.0 at Release 1 (R1) provides functions of patient management, image acquisition, visualization and analysis capabilities that are categorized into the following groups:

- Patient Management and Administration
- Acquisition
- Analysis

CZSC has implemented a software development process according to IEC 62304. With software version 2.0 at Release 1 (R1), PRIMUS offers automatic retinal thickness measurement and quantitative analysis reports.

Risk Management and General Safety and Effectiveness

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Risk management is ensured via a risk analysis, which is used to identify potential hazards and mitigations. These potential hazards are controlled by software means, user instructions, verification of requirements and validation of the clinical workflow to ensure that the product meets its intended uses. To minimize electrical, mechanical and radiation hazards, ZEISS adheres to recognized and established industry practice and relevant international standards.

Technological Characteristics and Substantial Equivalence (21 CFR §807.92(a)(6)):

It is the opinion of Carl Zeiss Meditec, Incorporated that the proposed device, the PRIMUS 200, is substantially equivalent to the CIRRUS HD-OCT with Software Version 6.0.

The indications for use for the PRIMUS 200 is similar to the indications for the predicate device CIRRUS HD-OCT with Software Version 6.0.

A technological comparison and clinical testing demonstrate that the PRIMUS 200 system is functionally equivalent to the primary predicate CIRRUS HD-OCT (K111157) and does not raise new questions regarding safety and effectiveness.

Summary of Verification and Validation Activity (21 CFR §807.92(b)):

Bench Testing (21 CFR §807.92(b)(1))

Bench testing in the form of Unit, Integration and System Integration testing was performed to evaluate the performance and functionality of the software version 2.0. The System level software verification and regression testing has been performed successfully to meet their previously determined acceptance criteria as stated in the Test Plans.

PRIMUS is designed and tested to applicable standards for electrical and optical safety with established specifications. Performance testing conducted on the PRIMUS instrument was consistent to the intended use claim. The verification testing demonstrates that the device performance complies with specifications and requirements. Results of verification and validation demonstrate safety and effectiveness as the predicate device, tests can be categorized into the following groups:

- Device System Verification
- Verification According to Harmonized/Recognized Standards
    - Electrical Safety and Electromagnetic Compatibility
    - Environmental Simulation
    - Usability
    - Biocompatibility
- Software Verification and Validation
- Product Validation

Testing to Consensus Standards (21 CFR §807.92(b)(1))

The PRIMUS 200 system has been tested (as needed) to meet the requirements for conformity (where applicable) to multiple industry standards. The R&D evaluation of the relevant testing to consensus standards is documented.

Substantial Equivalence to Predicates (21 CFR §807.92(b)(1))

Verification testing to the system requirements (SRS) for the PRIMUS 200 system and the validation of the intended use is intended to support the claim of substantial equivalence to the following Substantial Equivalence table:

Table 1: Substantial Equivalence Table

Device	**PRIMUS (Proposed Device K163195)**	**Cirrus HD-OCT with Retinal Nerve Fiber Layer (RNFL), Macular, Optic Nerve Head and Ganglion Cell Normative Database (K111157) [Model: 4000]**
Intended Use	The PRIMUS is used for in-vivo viewing of axial cross-sectional imaging and measurement of posterior ocular structures.	The Cirrus™ HD-OCT with Retinal Nerve Fiber Layer (RNFL), Macular, Optic Nerve Head and Ganglion Cell Normative Databases is indicated for in-vivo viewing, axial cross-sectional, and three-dimensional imaging and measurement of anterior and posterior ocular structures.
Indication for Use	The PRIMUS instrument is a non-contact, high resolution tomographic and biomicroscopic imaging device. It is indicated for in-vivo viewing of axial cross sections and measurement of posterior ocular structures, including retina, retinal nerve fiber layer, macula, and optic disc. It is intended for use 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	The Cirrus™ HD-OCT is a non-contact, high resolution tomographic and biomicroscopic imaging device. It is indicated for in-vivo viewing, axial cross-sectional, and three-dimensional imaging and measurement of anterior and posterior ocular structures, including cornea, retina, retinal nerve fiber layer, ganglion cell plus inner plexiform layer, macula, and optic nerve head. The Cirrus normative databases are quantitative tools 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. The Cirrus HD-OCT is intended for use 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
Device Classification Name	Optical Coherence Tomography (OCT)	Optical Coherence Tomography (OCT)
Generic Common Name	Optical Coherence Tomography (OCT)	Optical Coherence Tomography (OCT)
Classification Product Code	OBO	OBO
Class	II	II
Technology	Spectral Domain OCT (SD-OCT)	Spectral Domain OCT (SD-OCT)
OCT Imaging		
Methodology	Spectral Domain OCT (SD-OCT)	Spectral Domain OCT (SD-OCT)
Optical Source	Super Luminescent Diode, 840nm	Super Luminescent Diode, 840nm
Optical Power	≤ 725 µW at the cornea	< 725 µW at the cornea
Scan Speed	12,000 (±10%) A-scans per second	27,000 A-scans per second
A-Scan Depth	2.0 mm (in tissue), 1,024 points	2.0 mm (in tissue), 1,024 points
Axial Resolution	5 µm ±1 (in tissue)	5 µm (in tissue)
Transverse Resolution	< 20µm (in tissue, FWHM*)	15 µm (in tissue)

Table 1: Substantial Equivalence Table

Device	**PRIMUS (Proposed Device K163195)**	**Cirrus HD-OCT with Retinal Nerve Fiber Layer (RNFL), Macular, Optic Nerve Head and Ganglion Cell Normative Database (K111157) [Model: 4000]**
Scan Pixels	1024 axial x (128-1024) transverse	1024 axial × (200-4096) transverse
Acquisition Time	Up to 2.5 seconds (depending on # of pixels scanned)	Up to 2.9 sec (depending on # of pixels scanned)
Scan Patterns	5-line raster scan, 1-line HD scan, Macular Cube scan (512x32), ONH/RNFL cube scan (128x128)	Line, circle, cross-hair, raster (a series of closely spaced lines), radial scans and combinations of the above. Includes Macular Cube Scan (512x128); ONH/RNFL Cube Scan (200x200); HD 5-line raster; HD Single line scan
Fundus Imaging		
Methodology	Confocal Scanning "Laser" Ophthalmoscope (cSLO)	Line Scanning Ophthalmoscope
Optical Source	Super Luminescent Diode (SLD), 840nm	Super Luminescent Diode (SLD), 750 nm
Optical Power	≤ 725µW at the cornea	< 1.5 mW at the cornea
Field of View	29 × 21 degrees (W × H)	36 × 30 degrees (W × H)
Frame Rate	Alignment: ≥ 4.0 Hz	> 20 Hz
Transverse Resolution	Alignment : ≤ 80µm (in Tissue)	25 µm (in tissue)
Fixation		
Internal Fixation Source	Consistently displayed 525 nm Green colored LED	LCD (green pixels)
Internal Fixation Focus Adjustment	-23D to +17D (diopters) Focus of Internal Fixation will change according to different refractive error adjustment	-20D to +20D (diopters)
External Fixation Source	Mechanically adjustable arm with blinking LED at the tip	Mechanically adjustable arm with blinking LED at the tip

CLINICAL EVALUATION

Clinical evaluation performed on the PRIMUS supports the indications for use statement and demonstrates that the device is substantially equivalent to the predicate device and does not raise new questions regarding safety and effectiveness.

A prospective study was conducted to support the indication for use statement for the PRIMUS with software version 2.0 at Release 1 (R1) and to determine comparability of the measurements obtained from both the PRIMUS 200 and the Cirrus HD-OCT Model 4000 instruments. Clinical data was collected and analyzed to determine the repeatability and reproducibility of the measurements of the PRIMUS 200. The study enrolled normal eyes, eyes with retinal disease and glaucoma.

Comparative analysis for the PRIMUS 200 and CIRRUS Model 4000

A study was performed on total 127 subjects, which included 45 normal subjects, 39 retinal disease subjects and 43 glaucoma subjects were analyzed in the study to evaluate equivalence of the means of 19 measurement parameters: retinal nerve fiber layer (RNFL) thickness (5 parameters), optic nerve head (ONH) (5 parameters), and macular thickness (9 parameters) between the PRIMUS 200 and Cirrus HD-OCT Model 4000.

Two study devices, PRIMUS 200 & Cirrus HD-OCT Model 4000 and each measurement parameter, the mean of the available measurements was calculated for each study eye. The difference in each of the 19 measurement parameters between the PRIMUS 200 and Cirrus HD-OCT Model 4000 was calculated for each study eye. The mean difference, the corresponding 95% confidence intervals, and 95% limits of agreement were calculated for each measurement parameter. The comparative analyses utilized on one PRIMUS 200 device, and the results are presented in Tables 2, 3 and 4 for the normal, retinal disease and glaucoma disease eye studies, respectively. Additionally 95% CIs for the lower and upper limits of agreement are provided in Table 2a (normal eyes), Table 3a (retinal disease eyes) and Table 4a (glaucomatous eyes).

The mean values of the 19 thickness parameters were very similar between the two devices. The results of the study parameters demonstrate substantial equivalence between the PRIMUS 200 and Cirrus HD-OCT Model 4000.

Table 2: Mean difference in macular thickness, RNFL thickness and ONH measurements between PRIMUS 200 and CIRRUS 4000 (Normal eyes)

	Primus 200 Mean (SD)	Cirrus 4000 Mean (SD)	Difference Mean (SD)	95% Confidence Interval of Mean Difference	95% Limits of Agreement for Differences Between Subject Means
Macular Thickness Parameters (N=45)					
Central Subfield (µm)	236.1 (19.87)	236.0 (20.77)	0.1 (5.36)	(-1.5, 1.7)	(-10.4, 10.6)
Inner Nasal (µm)	315.1 (17.16)	316.2 (18.14)	-1.1 (6.74)	(-3.1, 0.9)	(-14.3, 12.1)
Inner Superior (µm)	311.9 (16.11)	315.6 (16.47)	-3.8 (6.30)	(-5.6, -2.0)	(-16.1, 8.5)
Inner Temporal (µm)	299.4 (16.59)	301.5 (16.49)	-2.1 (6.25)	(-3.9, -0.3)	(-14.3, 10.2)
Inner Inferior (µm)	309.6 (16.80)	312.4 (16.96)	-2.8 (6.44)	(-4.7, -0.9)	(-15.4, 9.8)
Outer Nasal (µm)	291.0 (13.47)	293.9 (14.08)	-3.0 (4.96)	(-4.4, -1.6)	(-12.7, 6.7)
Outer Superior (µm)	273.5 (11.67)	274.1 (10.37)	-0.6 (6.71)	(-2.6, 1.4)	(-13.8, 12.6)
Outer Temporal (µm)	252.7 (12.81)	255.6 (12.02)	-2.9 (5.11)	(-4.4, -1.4)	(-12.9, 7.1)
Outer Inferior (µm)	258.0 (12.18)	262.8 (13.37)	-4.8 (3.78)	(-5.9, -3.7)	(-12.2, 2.6)
RNFL Thickness Parameters (N=45)					
Average RNFL Thickness (µm)	90.6 (10.03)	92.8 (10.00)	-2.3 (4.05)	(-3.5, -1.1)	(-10.2, 5.6)
Temporal (µm)	58.4 (6.11)	59.7 (8.65)	-1.2 (5.49)	(-2.8, 0.4)	(-12.0, 9.6)
Superior (µm)	115.5 (16.88)	118.0 (16.64)	-2.5 (7.41)	(-4.7, -0.3)	(-17.0, 12.0)
Nasal (µm)	71.7 (9.86)	74.2 (10.93)	-2.5 (5.06)	(-4.0, -1.0)	(-12.4, 7.4)
Inferior (µm)	116.6 (17.20)	119.5 (16.31)	-2.8 (7.14)	(-4.9, -0.7)	(-16.8, 11.2)
ONH Parameters (N=45)					
Rim Area (mm^2)	1.29 (0.194)	1.31 (0.184)	-0.02 (0.057)	(-0.04, 0.00)	(-0.13, 0.09)
Disc Area (mm^2)	1.94 (0.337)	1.96 (0.341)	-0.02 (0.089)	(-0.05, 0.01)	(-0.19, 0.15)
Average Cup-to-Disc Ratio	0.54 (0.143)	0.53 (0.148)	0.01 (0.026)	(0.00, 0.02)	(-0.04, 0.06)
Vertical Cup-to-Disc Ratio	0.52 (0.138)	0.51 (0.145)	0.01 (0.031)	(0.00, 0.02)	(-0.05, 0.07)
Cup Volume (mm^3)	0.21 (0.149)	0.20 (0.148)	0.00 (0.018)	(-0.01, 0.01)	(-0.04, 0.04)

95% Confidence Interval of Mean Difference = mean ± 1.96 x SE.
95% Limits of Agreement = mean ± 1.96 x SD.

Table 2a: 95% Limits of Agreement for Difference between PRIMUS 200 and CIRRUS 4000 Means, 95% CIs for the Limits of Agreement (Normal eyes)

	95% Limits of Agreement for Differences Between Subject Means	95% Confidence Interval for Lower Limit of Agreement	95% Confidence Interval for Upper Limit of Agreement
Macular Thickness Parameters (N = 45)			
Central Subfield (µm)	(-10.4, 10.6)	(-13.1, -7.7)	(7.9, 13.3)
Inner Nasal (µm)	(-14.3, 12.1)	(-17.7, -10.9)	(8.7, 15.5)
Inner Superior (µm)	(-16.1, 8.5)	(-19.3, -12.9)	(5.3, 11.7)
Inner Temporal (µm)	(-14.3, 10.2)	(-17.5, -11.1)	(7.0, 13.4)
Inner Inferior (µm)	(-15.4, 9.8)	(-18.7, -12.1)	(6.5, 13.1)
Outer Nasal (µm)	(-12.7, 6.7)	(-15.2, -10.2)	(4.2, 9.2)
Outer Superior (µm)	(-13.8, 12.6)	(-17.2, -10.4)	(9.2, 16.0)
Outer Temporal (µm)	(-12.9, 7.1)	(-15.5, -10.3)	(4.5, 9.7)
Outer Inferior (µm)	(-12.2, 2.6)	(-14.1, -10.3)	(0.7, 4.5)
RNFL Parameter (N = 45)			
Average RNFL Thickness (µm)	(-10.2, 5.6)	(-12.2, -8.2)	(3.6, 7.6)
Temporal (µm)	(-12.0, 9.6)	(-14.8, -9.2)	(6.8, 12.4)
Superior (µm)	(-17.0, 12.0)	(-20.7, -13.3)	(8.3, 15.7)
Nasal (µm)	(-12.4, 7.4)	(-15.0, -9.8)	(4.8, 10.0)
Inferior (µm)	(-16.8, 11.2)	(-20.4, -13.2)	(7.6, 14.8)
ONH Parameters (N = 45)			
Rim Area (mm^2)	(-0.13, 0.09)	(-0.16, -0.10)	(0.06, 0.12)
Disc Area (mm^2)	(-0.19, 0.15)	(-0.24, -0.14)	(0.10, 0.20)
Average Cup-to-Disc Ratio	(-0.04, 0.06)	(-0.05, -0.03)	(0.05, 0.07)
Vertical Cup-to-Disc Ratio	(-0.05, 0.07)	(-0.07, -0.03)	(0.05, 0.09)
Cup Volume (mm^3)	(-0.04, 0.04)	(-0.05, -0.03)	(0.03, 0.05)

95% Limits of Agreement = mean ± 1.96 x SD.
95% Confidence Interval of (Lower/Upper) Limit of Agreement = (Lower/Upper) Limit ± 1.96 x √3*SE.

Table 3: Mean difference in macular thickness measurements between PRIMUS 200 and CIRRUS 4000 (Retinal disease eyes)

	Primus 200 Mean (SD)	Cirrus 4000 Mean (SD)	Difference Mean (SD)	95% Confidence Interval of Mean Difference	95% Limits of Agreement for Differences Between Subject Means
Macular Thickness Parameters (N=39)					
Central Subfield (µm)	308.8 (113.31)	307.0 (114.32)	1.8 (22.06)	(-5.1, 8.7)	(-41.4, 45.0)
Inner Nasal (µm)	353.2 (71.61)	354.2 (67.90)	-0.9 (12.28)	(-4.8, 3.0)	(-25.0, 23.2)
Inner Superior (µm)	349.8 (71.23)	352.0 (70.01)	-2.2 (16.04)	(-7.2, 2.8)	(-33.6, 29.2)
Inner Temporal (µm)	346.5 (85.67)	348.8 (87.22)	-2.3 (15.13)	(-7.0, 2.4)	(-32.0, 27.4)
Inner Inferior (µm)	353.2 (81.13)	356.3 (82.62)	-3.1 (14.72)	(-7.7, 1.5)	(-32.0, 25.8)
Outer Nasal (µm)	322.6 (53.88)	324.5 (54.96)	-1.9 (7.22)	(-4.2, 0.4)	(-16.1, 12.3)
Outer Superior (µm)	311.6 (70.11)	309.9 (72.34)	1.7 (10.69)	(-1.7, 5.1)	(-19.3, 22.7)
Outer Temporal (µm)	289.3 (67.34)	291.9 (65.99)	-2.6 (11.64)	(-6.3, 1.1)	(-25.4, 20.2)
Outer Inferior (µm)	296.0 (70.34)	302.2 (70.65)	-6.2 (9.34)	(-9.1, -3.3)	(-24.5, 12.1)

95% Confidence Interval of Mean Difference = mean ± 1.96 x SE.
95% Limits of Agreement = mean ± 1.96 x SD.

Table 3a: 95% Limits of Agreement for Difference between PRIMUS 200 and CIRRUS 4000 Means of Macular Thickness Measurements, 95% CIs for the Limits of Agreement (Retinal disease eyes)

	95% Limits of Agreement for Differences Between Subject Means	95% Confidence Interval for Lower Limit of Agreement	95% Confidence Interval for Upper Limit of Agreement
Macular Thickness Parameters (N = 39)			
Central Subfield (µm)	(-41.4, 45.0)	(-53.4, -29.4)	(33.0, 57.0)
Inner Nasal (µm)	(-25.0, 23.2)	(-31.7, -18.3)	(16.5, 29.9)
Inner Superior (µm)	(-33.6, 29.2)	(-42.3, -24.9)	(20.5, 37.9)
Inner Temporal (µm)	(-32.0, 27.4)	(-40.2, -23.8)	(19.2, 35.6)
Inner Inferior (µm)	(-32.0, 25.8)	(-40.0, -24.0)	(17.8, 33.8)
Outer Nasal (µm)	(-16.1, 12.3)	(-20.0, -12.2)	(8.4, 16.2)
Outer Superior (µm)	(-19.3, 22.7)	(-25.1, -13.5)	(16.9, 28.5)
Outer Temporal (µm)	(-25.4, 20.2)	(-31.7, -19.1)	(13.9, 26.5)
Outer Inferior (µm)	(-24.5, 12.1)	(-29.6, -19.4)	(7.0, 17.2)

95% Limits of Agreement = mean ± 1.96 x SD.
95% Confidence Interval of (Lower/Upper) Limit of Agreement = (Lower/Upper) Limit ± 1.96 x √3*SE.

Table 4: Mean difference in RNFL thickness and ONH measurements between PRIMUS 200 and CIRRUS 4000 (Glaucomatous eyes)

	Primus 200 Mean (SD)	Cirrus 4000 Mean (SD)	Difference Mean (SD)	95% Confidence Interval of Mean Difference	95% Limits of Agreement for Differences Between Subject Means
RNFL Parameters (N=43)					
Average RNFL Thickness (µm)	71.0 (15.00)	72.3 (15.78)	-1.4 (3.34)	(-2.4, -0.4)	(-7.9, 5.1)
Temporal (µm)	55.5 (11.51)	54.3 (9.72)	1.2 (7.62)	(-1.1, 3.5)	(-13.7, 16.1)
Superior (µm)	85.2 (25.96)	87.4 (25.51)	-2.1 (6.50)	(-4.0, -0.2)	(-14.8, 10.6)
Nasal (µm)	61.8 (9.16)	64.8 (12.94)	-3.0 (6.44)	(-4.9, -1.1)	(-15.6, 9.6)
Inferior (µm)	81.6 (26.11)	82.8 (26.17)	-1.2 (5.80)	(-2.9, 0.53)	(-12.6, 10.2)
ONH Parameters (N=43)					
Rim Area (mm^2)	0.83 (0.301)	0.82 (0.300)	0.00 (0.074)	(-0.02, 0.02)	(-0.15, 0.15)
Disc Area (mm^2)	2.07 (0.367)	2.05 (0.345)	0.02 (0.110)	(-0.01, 0.05)	(-0.20, 0.24)
Average Cup-to-Disc Ratio	0.77 (0.106)	0.76 (0.107)	0.00 (0.022)	(-0.01, 0.01)	(-0.04, 0.04)
Vertical Cup-to-Disc Ratio	0.76 (0.097)	0.75 (0.103)	0.00 (0.037)	(-0.01, 0.01)	(-0.07, 0.07)
Cup Volume (mm^3)	0.60 (0.333)	0.59 (0.335)	0.01 (0.044)	(0.00, 0.02)	(-0.08, 0.10)

95% Confidence Interval of Mean Difference = mean ± 1.96 x SE.
95% Limits of Agreement = mean ± 1.96 x SD.

Table 4a: 95% Limits of Agreement for Difference between PRIMUS 200 and CIRRUS 4000 Means of RNFL thickness and ONH Measurements, 95% CIs for the Limits of Agreement (Glaucomatous eyes)

	95% Limits of Agreement for Differences Between Subject Means	95% Confidence Interval for Lower Limit of Agreement	95% Confidence Interval for Upper Limit of Agreement
RNFL Parameter (N = 43)			
Average RNFL Thickness (µm)	(-7.9, 5.1)	(-9.6, -6.2)	(3.4, 6.8)
Temporal (µm)	(-13.7, 16.1)	(-17.6, -9.8)	(12.2, 20.0)
Superior (µm)	(-14.8, 10.6)	(-18.2, -11.4)	(7.2, 14.0)
Nasal (µm)	(-15.6, 9.6)	(-18.9, -12.3)	(6.3, 12.9)
Inferior (µm)	(-12.6, 10.2)	(-15.6, -9.6)	(7.2, 13.2)
ONH Parameters (N = 43)			
Rim Area (mm^2)	(-0.15, 0.15)	(-0.19, -0.11)	(0.11, 0.19)
Disc Area (mm^2)	(-0.20, 0.24)	(-0.26, -0.14)	(0.18, 0.30)
Average Cup-to-Disc Ratio	(-0.04, 0.04)	(-0.05, -0.03)	(0.03, 0.05)
Vertical Cup-to-Disc Ratio	(-0.07, 0.07)	(-0.09, -0.05)	(0.05, 0.09)
Cup Volume (mm^3)	(-0.08, 0.10)	(-0.10, -0.06)	(0.08, 0.12)

95% Limits of Agreement = mean ± 1.96 x SD.
95% Confidence Interval of (Lower/Upper) Limit of Agreement = (Lower/Upper) Limit ± 1.96 x $\sqrt{3}$*SE.

Repeatability and Reproducibility Study on the PRIMUS 200

A study was performed to determine the repeatability and reproducibility of the measurements of the PRIMUS 200 by analyzing 125 subjects, which included 44 normal subjects, 38 retinal disease subjects and 43 glaucoma subjects.

Analysis of variance (ANOVA) with the mixed-effects model was used for the inter-device/operator variability, repeatability SD, the repeatability limit, repeatability % COV, and interaction between subject and device/operator variability of each measurement parameter. Since each operator was assigned to a single PRIMUS 200 device, the inter-operator and inter-device variability were not estimated separately. The repeatability and reproducibility standard deviation (SD) and limits for the PRIMUS 200 are shown in Tables 4 and 5. PRIMUS 200 showed good repeatability and reproducibility for both normal and diseased eyes.

Table 5: PRIMUS 200 repeatability and reproducibility in measuring macular thickness RNFL thickness and ONH parameters (Normal eyes)

Parameter	PRIMUS 200					
	Repeatability			Reproducibility		
	SD	Limit	COV %	SD	Limit	COV %
Macular Thickness Parameters (N = 44)						
Central Subfield (µm)	3.02	8.46	1.29	4.63	12.96	1.97
Inner Nasal (µm)	2.81	7.87	0.90	5.52	15.46	1.77
Inner Superior (µm)	3.30	9.24	1.07	5.53	15.48	1.79
Inner Temporal (µm)	2.79	7.81	0.94	5.21	14.59	1.75
Inner Inferior (µm)	3.01	8.43	0.98	5.14	14.39	1.67
Outer Nasal (µm)	2.73	7.64	0.94	4.75	13.30	1.64
Outer Superior (µm)	4.82	13.50	1.76	6.18	17.30	2.26
Outer Temporal (µm)	3.03	8.48	1.20	4.98	13.94	1.97
Outer Inferior (µm)	3.20	8.96	1.25	4.63	12.95	1.80
RNFL Thickness Parameters (N = 44)						
Avg. RNFL Thickness (µm)	1.93	5.40	2.12	2.51	7.03	2.76
Temporal (µm)	2.96	8.29	5.01	3.38	9.46	5.72
Superior (µm)	3.64	10.19	3.14	5.15	14.42	4.44
Nasal (µm)	3.35	9.38	4.57	3.91	10.95	5.33
Inferior (µm)	3.79	10.61	3.29	5.38	15.06	4.66
ONH Parameters (N = 44)						
Rim Area (mm^2)	0.037	0.104	2.839	0.048	0.134	3.683
Disc Area (mm^2)	0.058	0.162	2.957	0.072	0.202	3.671
Average CD Ratio	0.010	0.028	1.844	0.013	0.036	2.397
Vertical Cup-to-Disc Ratio	0.017	0.048	3.308	0.019	0.053	3.698
Cup Volume (mm^3)	0.014	0.039	6.702	0.016	0.045	7.660

Per ISO 5725-1 and ISO 5725-6, Repeatability Limit = 2.8 × Repeatability SD.
Reproducibility SD is the standard deviation under reproducibility conditions. It was estimated by the square root of the sum of repeatability variance and the variance components of operator, operator*subjects, device and device*subjects.

Reproducibility Limit is the upper 95 % limit for the difference between repeated results under reproducibility conditions.
Reproducibility Limit = 2.8 ×reproducibility SD.
COV = Coefficient of Variation = SD □□Mean. □□100. SD is either Repeatability SD or Reproducibility SD.

Table 6: PRIMUS 200 repeatability and reproducibility in measuring macular thickness RNFL thickness and ONH parameters (Diseased eyes)

Parameter	PRIMUS 200					
	Repeatability			Reproducibility		
	SD	Limit	COV %	SD	Limit	COV %
Macular Thickness Parameters (N = 38)						
Central Subfield (µm)	12.31	34.47	4.02	13.84	38.75	4.52
Inner Nasal (µm)	5.37	15.04	1.54	6.46	18.09	1.85
Inner Superior (µm)	7.05	19.74	2.04	8.42	23.58	2.43
Inner Temporal (µm)	7.22	20.22	2.10	9.40	26.32	2.73
Inner Inferior (µm)	4.48	12.54	1.28	6.88	19.26	1.96
Outer Nasal (µm)	3.66	10.25	1.14	5.10	14.28	1.59
Outer Superior (µm)	4.16	11.65	1.34	5.08	14.22	1.64
Outer Temporal (µm)	4.73	13.24	1.63	7.69	21.53	2.65
Outer Inferior (µm)	4.35	12.18	1.47	5.17	14.48	1.75
RNFL Thickness Parameters (N = 43)						
Avg. RNFL Thickness (µm)	2.12	5.94	3.02	2.73	7.64	3.89
Temporal (µm)	3.34	9.35	6.10	4.58	12.82	8.36
Superior (µm)	4.67	13.08	5.56	5.74	16.07	6.83
Nasal (µm)	3.47	9.72	5.57	4.19	11.73	6.72
Inferior (µm)	4.47	12.52	5.60	5.39	15.09	6.75
ONH Parameters (N = 43)						
Rim Area (mm^2)	0.050	0.140	6.028	0.055	0.154	6.631
Disc Area (mm^2)	0.098	0.274	4.733	0.105	0.294	5.072
Average CD Ratio	0.014	0.039	1.829	0.016	0.045	2.091
Vertical Cup-to-Disc Ratio	0.024	0.067	3.173	0.025	0.070	3.305
Cup Volume (mm^3)	0.051	0.143	8.645	0.052	0.146	8.814

Per ISO 5725-1 and ISO 5725-6, Repeatability Limit = 2.8 × Repeatability SD.
Reproducibility SD is the standard deviation under reproducibility conditions. It was estimated by the square root of the sum of repeatability variance and the variance components of operator, operator*subjects, device and device*subjects.
Reproducibility Limit is the upper 95 % limit for the difference between repeated results under reproducibility conditions.
Reproducibility Limit = 2.8 × Reproducibility SD.
COV = Coefficient of Variation = SD ÷ Mean. × 100. SD is either Repeatability SD or Reproducibility SD.

510(k) Summary (21 CFR §807.92(c))

As described in this 510(k) Summary, all testing deemed necessary was conducted on the PRIMUS 200 with Software Version 2.0 to ensure that the device is safe and effective for its intended use when used in accordance with its Instructions for Use and substantially equivalent to, and performs as well as, the predicate device