



Food and Drug Administration
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October 26, 2016

Carl Zeiss Meditec, Inc.
Ms. Christine Dunbar
Manager, Regulatory Submissions
5160 Hacienda Drive
Dublin, CA 94568

Re: K161194
Trade/Device Name: Plex Elite 9000 SS-OCT
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO
Dated: September 12, 2016
Received: September 13, 2016

Dear Ms. Dunbar:

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 yours,


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

Indications for Use

510(k) Number (if known)

K161194

Device Name

PLEX™ Elite 9000 SS-OCT

Model 9000

Indications for Use (Describe)

The PLEX™ Elite 9000 Swept-Source OCT [SS-OCT] is a non-contact, high resolution, wide field of view tomographic and biomicroscopic imaging device intended for in-vivo viewing, axial cross-sectional and three-dimensional imaging of posterior ocular structures. The device is indicated for visualizing posterior ocular structures including, but not limited to, retina, retinal nerve fiber layer, ganglion cell plus inner plexiform layer, macula, optic nerve head, vitreous and choroid.

The PLEX™ Elite SS-OCT angiography is indicated as an aid in the visualization of vascular structures of the retina and choroid.

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

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**510(k) SUMMARY
(Per 21 CFR §807.92)**

PLEX™ Elite 9000 Swept-Source OCT
With Software Version 1.0

GENERAL INFORMATION

Manufacturer: Carl Zeiss Meditec, Inc.
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Date Summary Prepared: October 21, 2016

Classification name: Tomography, Optical Coherence; Ophthalmoscope

Classification: Class II (acc. 21 CFR 886.1570)

Product Code: OBO

Trade/Proprietary name: PLEX Elite 9000 SS-OCT

Common Name Swept Source Optical Coherence Tomography System

Substantial Equivalence Claimed To (21 CFR §807.92(a)(3))

Company: Carl Zeiss Meditec, Inc.
Device: CIRRUStm HD-OCT (K150977)

Reference Predicate:
Company: Carl Zeiss Meditec AG
Device: IOLMaster 700 (K143275)

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The PLEX Elite 9000 SS-OCT system as described in this premarket notification has the similar intended use, indications for use, and fundamental scientific technical characteristics as the predicate and reference devices listed above.

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

Intended Use Statement:

The PLEX™ Elite 9000 Swept-Source OCT [SS-OCT] is a non-contact, high resolution, wide field of view tomographic and biomicroscopic imaging device intended for in-vivo viewing, axial cross-sectional and three-dimensional imaging of posterior ocular structures.

Indications for Use Statement:

The PLEX™ Elite 9000 Swept-Source OCT [SS-OCT] is a non-contact, high resolution, wide field of view tomographic and biomicroscopic imaging device intended for in-vivo viewing, axial cross-sectional and three-dimensional imaging of posterior ocular structures. The device is indicated for visualizing posterior ocular structures including, but not limited to, retina, retinal nerve fiber layer, ganglion cell plus inner plexiform layer, macula, optic nerve head, vitreous and choroid.

The PLEX™ Elite SS-OCT angiography is indicated as an aid in the visualization of vascular structures of the retina and choroid.

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

The PLEX™ Elite 9000 SS-OCT is a computerized instrument that acquires cross-sectional tomograms of the posterior ocular structures (including cornea, retina, retinal nerve fiber layer, macula, and optic disc). It employs non-invasive, non-contact, low-coherence interferometry to obtain these high-resolution images. Using this non-invasive optical technique, the PLEX Elite SS-OCT produces high-resolution cross-sectional tomograms of the eye without contacting the eye. It also produces images of the retina and layers of the retina from an *en face* perspective (i.e., as if looking directly in the eye) and non-contrast angiographic imaging of the retinal microvasculature.

The PLEX Elite 9000 SS-OCT is offered in one model, the Elite 9000 in a new compact desktop system. The PLEX Elite SS-OCT contains a swept source, Class 1 Laser system operating at 1060 nm and includes a new system computer and archive with up to 24 TB storage capacity. The PLEX Elite also contains an iris viewer, fixation system and the fundus camera is a similar line-scanning ophthalmoscope (LSO) as used on the CIRRUS HD-OCT system, model 4000.

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New Features consist of the following:

- **New → Swept Source OCT system in a compact, desktop system.**
- **New → Swept Source Laser system, operating at 1060 nm wavelength, acquiring 100,000 A-Scans a second.** The new PLEX Elite 9000 system utilizes the same OEM swept source laser system as the IOLMaster 700¹ and is a computerized instrument that acquires and analyzes cross-sectional tomograms of anterior and posterior ocular structures (including cornea, retina, retinal nerve fiber layer, macula, and optic disc). It employs non-invasive, non-contact, low-coherence interferometry to obtain high-resolution images. It produces images of the retina and layers of the retina from an *en face* perspective and supports the acquisition of angiographic data to evaluate the microvasculature of the retina without the use of intravenous contrast agents.
- **New → High Definition Scan:**
 - **HD 1 Line 10 x 100 Spotlight Scan, a 1 - high-definition single line scan -** This scan generates a single ultra-high definition scan at a depth of 2.0 mm by averaging from 10 to 100 B-scans, each composed of 1536 A-scans. The scan can be positioned anywhere on the fundus image
- **Updated → FastTrac™ 2.0 Retinal Tracking Technology -** The PLEX Elite 9000 uses multiple channels of concurrent imaging and proprietary algorithms to monitor and correct for the motion of the eye in real-time. The motion of the retina is observed at a high rate to ensure higher efficiency in reducing the effects of motion; FastTrac ensures faster data acquisition by only re-scanning selective data that might be affected by motion. FastTrac also allows precise scanning at follow-up visits to acquire data at the same region of the eye.
- **Updated → En Face Analysis and Macular Cube Scans:** Automatically finds and displays retinal layers in existing 12x12 mm macular cube scans, including the optic nerve head (512x512 or 800x800 or 1024x1024) scans. The user can visualize *en face* (*c-scan*), or partial *en face*, views of the same data. The user can choose any of the three surfaces as the basis for the partial *en face* images. A partial *en face* image is formed by the summation of image intensities based on one or more retinal contours.
- **Updated → OCT Angiography:** PLEX Elite SS-OCT Angiography images are processed to provide detailed images of ocular blood flow without the use of intravenous dyes to visualize microvasculature structures of the eye. The flow data that is generated by processing OCT images with OMAG^c has the same resolution and axial and transverse

¹ Note, due to differences in the intended use of the IOLMaster 700 (Biometry for anterior structures and OCT imaging for Axial length and Fixation) and the PLEX Elite 9000 (OCT imaging for posterior ocular structures and angiography) the implementation of the SS-OCT Engine is different.

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extent as the OCT intensity and phase data, and therefore depth resolved flow images can be generated and displayed.

- **Updated** → **Angio PLEX™ OCT Angiography**
(Market name for PLEX Elite 9000, SS-OCT Angiography)

A series of studies were performed comparing CIRRUS OCT angiography scans of 3x3 mm and 6x6 mm with the PLEX Elite SS-OCT angiography scans of the same dimensions. The findings demonstrate that the PLEX Elite Angiography, in combination with OCT OMAG Complex (intensity and phase) processing, can produce non-invasive three-dimensional information regarding retinal microvasculature with a higher signal-to-noise ratio and an increased depth of penetration as compared to the CIRRUS OCT angiography with intensity only processing.

AngioPLEX Angiography is not intended as a substitute for fluorescein angiography. Vascular findings on fluorescein angiography may be absent, poorly defined, or variably defined on AngioPLEX Angiography. Additionally, leakage, staining, and pooling are not features of AngioPLEX Angiography.

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 PLEX Elite 9000 SS-OCT system, is substantially equivalent to the CIRRUS HD-OCT with Software Version 8.0 supported by the IOLMaster 700 with an internal SS-OCT system.

The indications for use for the PLEX Elite 9000 is similar to the indications for the primary predicate device CIRRUS HD-OCT with Software Version 8.0.

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 1.0. The System level

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software verification and regression testing has been performed successfully to meet their previously determined acceptance criteria as stated in the Test Plans.

Non-Clinical Test Results (21 CFR §807.92(b)(2))

Non-clinical testing has been performed for the purpose of supporting technological claims for the improved signal-to-noise and penetration of the swept source laser system using a 1060 nm wavelength as compared to the same scans acquired on the predicate CIRRUS HD-OCT system using a SLD at 840 nm.

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

The PLEX Elite 9000 SS-OCT 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 PLEX Elite 9000 SS-OCT system and the validation of the intended use is intended to support the claim of substantial equivalence to the following primary predicate supported by the reference predicate:

Product Indications for Use	510(k) Clearance / Date	Claim of Equivalence for:
(Primary predicate) The CIRRUS™ HD-OCT is a non-contact, high resolution tomographic and biomicroscopic imaging device intended for in-vivo viewing, axial cross-sectional, and three-dimensional imaging of anterior and posterior ocular structures. The device is indicated for visualizing and measuring anterior and posterior ocular structures, including cornea, retina, retinal nerve fiber layer, ganglion cell plus inner plexiform layer, macula, and optic nerve head.	K150977 / September 01, 2015	The PLEX™ Elite 9000 Swept-Source OCT [SS-OCT] is a non-contact, high resolution, wide field of view tomographic and biomicroscopic imaging device intended for in-vivo viewing, axial cross-sectional and three-dimensional imaging of posterior ocular structures. The device is indicated for visualizing posterior ocular structures including, but not limited to, retina, retinal nerve fiber layer, ganglion cell plus inner plexiform layer, macula, optic nerve head, vitreous and choroid.
The CIRRUS OCT Angiography is indicated as an aid in the visualization of vascular structures of the retina and choroid.		The PLEX™ Elite SS-OCT angiography is indicated as an aid in the visualization of vascular structures of the retina and choroid.
The CIRRUS HD-OCT is indicated as a diagnostic device to aid in the detection and management of ocular diseases including, but not limited to, macular holes, cystoid macular edema, diabetic retinopathy, age-related macular degeneration, and glaucoma.		

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Product Indications for Use	510(k) Clearance / Date	Claim of Equivalence for:
<p>(Reference predicate) ZEISS IOLMaster 700</p> <p>The IOLMaster 700 is intended for biometric measurements and visualization of ocular structures. The measurements and visualization assist in the determination in the appropriate power and type of intraocular lens.</p> <p>The IOLMaster 700 employs non-invasive, non-contact low coherence interferometry (SS-OCT) to obtain cross-sectional images of the eye.</p>	<p>K143275 / July 10, 2015</p>	<p>PLEX™ Elite SS-OCT with Software Version 1.0 is a non-contact, high resolution, wide field of view tomographic and biomicroscopic imaging device intended for in-vivo viewing, axial cross-sectional and three-dimensional imaging of posterior ocular structures.</p>

Substantial Equivalence Table

Comparison Table of Predicate CIRRUS HD-OCT v8.0
And Proposed PLEX Elite 9000

Highlighted areas are New or Modified Technology for PLEX Elite 9000

Device	CIRRUS™ HD-OCT v8.0 (K150977) - Primary Predicate Device	PLEX™ Elite 9000 SS-OCT Proposed Device	Discussion
Intended Use	<p>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.</p>	<p>The PLEX™ Elite 9000 Swept-Source OCT [SS-OCT] is a non-contact, high resolution, wide field of view tomographic and biomicroscopic imaging device intended for in-vivo viewing, axial cross-sectional and three-dimensional imaging of posterior ocular structures.</p>	<p>Same intended use.</p>
Indications for Use	<p>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.</p> <p>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.</p>	<p>The PLEX™ Elite 9000 Swept-Source OCT [SS-OCT] is a non-contact, high resolution, wide field of view tomographic and biomicroscopic imaging device intended for in-vivo viewing, axial cross-sectional and three-dimensional imaging of posterior ocular structures.</p> <p>The device is indicated for visualizing posterior ocular structures including, but not limited to, retina, retinal nerve fiber layer, ganglion cell plus inner plexiform layer, macula, optic nerve head, vitreous and choroid.</p>	<p>Similar Indications for use.</p> <p>PLEX Elite does not contain a normative database in the R 1.0 release.</p>

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Device	CIRRUS™ HD-OCT v8.0 (K150977) - Primary Predicate Device	PLEX™ Elite 9000 SS-OCT Proposed Device	Discussion
	<p>The CIRRUS OCT angiography is indicated as an aid in the visualization of vascular structures of the retina and choroid.</p> <p>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.</p>	<p>The PLEX™ Elite SS-OCT angiography is indicated as an aid in the visualization of vascular structures of the retina and choroid.</p>	<p>Same Indications for Use for Angiography.</p>
Device Classification Name	Optical Coherence Tomographer (OCT)	Optical Coherence Tomographer (OCT)	Same
Technology	Spectral Domain (Spatially encoded Frequency Domain and Fourier Domain Principle) OCT	Spectral Domain (Time encoded Frequency Domain and Fourier Domain Principle) OCT	Similar purpose, change from spatial to time encoded spectra with new light source technology.
Illumination Sources used in Instrument	<ul style="list-style-type: none"> Light Emitting Diode 700 nm – Iris Viewer Super Luminescent Diode 750 nm - LSO Super Luminescent Diode 840 nm – OCT Imager 	<ul style="list-style-type: none"> Light Emitting Diode 700 nm - Iris Viewer Super Luminescent Diode 750 nm - LSO Swept Source Tunable Laser 1060 nm – OCT Imager 	<p>New laser light source and longer wavelength for similar imaging of the eye using a non-invasive optical technique produces high-resolution cross-sectional tomograms of the eye without contacting the eye.</p>
Laser Class Based on IEC 60825-1:2007	N/A	Class 1	Swept Source Laser is Class 1.
Optical Power	<0.775 mW at the cornea	<p>< 5.4 mW at the cornea*</p> <p>*controlled by an electronic safety interlock.</p>	<p>Different optical power allowed due to longer wavelength with the swept source laser light technology.</p>
Scan Speed	<p>27,000 A-scan points per second (Model 4000)</p> <p>27,000 A-scans/sec (Model 500)</p> <p>68,000 A-scans/sec: <i>Model 5000 only for OCT Angiography scans</i></p>	100,000 A-scan points per second for all scan types.	Similar purpose, increased scan speed due to change in detection technology (from CCD to a single channel detection).
Scan Speed	68,000 A-scan points per second (Model 5000)	100, 000 A-scans points per second	Similar purpose, increased scan speed due to change in detection technology (from CCD to a single channel detection). Higher density A-lines and B scan per acquisition.
OCT Angio-graphy feature			
Axial Scan Depth (Max)-Retina Cube scan	2.0 mm (in tissue), 1024 pixels per A-scans.	3.0 mm (in tissue), 1536 pixels per A-scans*	Same acquisition feature with same pixel size but larger matrix (more pixels) results in same pixel density and larger depth range.

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Device	CIRRUS™ HD-OCT v8.0 (K150977) - Primary Predicate Device	PLEX™ Elite 9000 SS-OCT Proposed Device	Discussion
Transverse Scan Range (Lateral range in degrees) Retina	10° x 0° on retina (Minimum) 31° x 31° on retina (Maximum)	14° x 0° on retina (Minimum line scan) 42° x 42° on retina (Cube) 56° x 0° on retina (Maximum line scan)	Same acquisition feature with an increased range due to minor change in technology.
Axial Scan Depth (Max)-Retina	2.0 mm (HD 1 Line (100x)) 1024 pixels (A-scans)	3.0 mm -HD 1 Line (10 x 100x) 1536 pixels per A-scans	Same acquisition feature with same pixel size but larger matrix (more pixels) results in same pixel density and larger depth range.
Axial Resolution	5 µm (in tissue)	5.5 µm (in tissue)	Similar resolution, change due to wavelength of imaging beam.
Transverse Resolution – Retina	≤ 15 µm (in tissue)	≤ 20 µm (in tissue)	Similar resolution, change in technology.
Scan Pixels Axial and Transverse sampling	1024 axial x (200-4096*) transverse *HD Raster Scans	1536 axial x (300-1024*) transverse *HD Spotlight and HD Cube scans	Similar imaging scans,
Acquisition Time	Up to 8 seconds without tracking (depending on number of pixels scanned)	Up to 12 seconds without tracking (depending on number of pixels scanned)	Acquiring more data (transverse density and axial length) per scan.
Scan types Non-Angio-graphy	Macular Cube 512 x 128 = 6 mm x 6 mm Macular Cube 200 x 200 = 6 mm x 6 mm Optic Disc Cube 200 x 200=6 mm x 6 mm HD (high-definition) -HD 1 Line (100x) -Enhanced Depth Imaging mode (EDI)	NEW →Macular Cube 512 x 512 = 12 mm x 12 mm NEW →Macular Cube 800 x 800 = 12 mm x 12 mm NEW →Macular Cube 1024 x 1024 =12 mm x 12 mm (All Mac Cube can include Optic Nerve Head) NEW →HD (high-definition) NEW →HD Single Line Scan (10x-100x) -Enhanced Depth Imaging mode (EDI)	Similar scan acquisition types, increased field of view due to change in imaging technology.
OCT Angio-graphy Cube	OCT Angiography: Where the matrix along the z axis is 1024 pixels Scans: 3x3 mm scans 6x6 mm scans	NEW →Where the matrix along the z axis is 1536 pixels. NEW →Scans: 3mmx3mm 6mmx6mm 9mmx9mm 12mmx12mm	Similar angiography scan acquisition types, increased field of view and density due to change in imaging technology.
Retina Tracking	FastTrac Feature Track-to-prior to Scan Acquisition tracking.	FastTrac Feature Track-to-prior to Scan Acquisition tracking.	Same
OCT Angio-graphy (aka OCTA)	<i>En Face</i> Algorithm - Modified to support Intensity and a flow cube (Angiography)	Modification → <i>En Face</i> Algorithm - Modified to support Intensity and Phase and a flow cube. NEW →Angiography OMAG Complex and a structure cube. Algorithm – Modified to support OMAG reconstruction.	Improved angiography algorithm, higher signal to noise, density and field of view due to change in technology.

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Device	CIRRUS™ HD-OCT v8.0 (K150977) - Primary Predicate Device	PLEX™ Elite 9000 SS-OCT Proposed Device	Discussion
ANALYSIS AND REPORTS			
<p>Cube Scan Display Macula Analysis</p> <p>Optic Nerve Head (ONH) analysis</p>	<p>Cube Scan Display:</p> <ul style="list-style-type: none"> ▪ Analyses for the Macula: <ul style="list-style-type: none"> - Macular thickness analysis - Macular 3D color thickness map ▪ Optic Nerve Head (ONH) analysis <ul style="list-style-type: none"> - Rim Area / Disc Area - Cup Volume - Neuro-retinal Rim Thickness - B-scan cross section of the ONH - B-scan slices and segmentation 	<p>Cube Scan Display:</p> <ul style="list-style-type: none"> ▪ Analyses for the Macula / ONH: <ul style="list-style-type: none"> - Macular 3D color thickness map <p>Macular Cube scans provide information about optic disc and fovea parameters including (but not limited to):</p> <ul style="list-style-type: none"> • Size (calipers) • Cup, disc, rim area and volume • Nerve fiber layer thickness • Ganglion cell layer thickness (macular cube) <p>In turn, scan Results screens (Review Scan Results) provide tools such as calipers for RNFL and Ganglion cell layer estimation.</p>	<p>Same basic features.</p>
<p>Advanced Visualization Display</p>	<ul style="list-style-type: none"> ▪ Advanced Visualization Display <ul style="list-style-type: none"> - Fundus Image with en face overlay - Slice navigators - Horizontal B-scan (X-image) - Vertical slice - A-scan (Y-image) - Top slab – C- scan (Z image) - Segmentation line toggle - Measurement calipers - Zoom controls - Save Image options - Movie option 	<ul style="list-style-type: none"> ▪ Advanced Visualization Display <ul style="list-style-type: none"> - Fundus Image with en face overlay - Slice navigators - Horizontal B-scan (X-image) - Vertical slice - A-scan (Y-image) - Top slab – C- scan (Z image) - Segmentation line toggle - Measurement calipers - Add Annotation - Zoom controls - Save Image options - Movie option - 3-D color Thickness map - NEW →Alternate Depth View - NEW →Thumbnail images 	<ul style="list-style-type: none"> ▪ Same basic features.
<p>HD Scans</p>	<p>HD 5-Line Raster HD 1 Line 100x HD 21 Line HD Radial HD Cross</p>	<p>Modification →HD Scan HD 1 Line 10 to 100x averaging</p> <p>See HD 1 Line 10 - 100x - Spotlight</p>	<p>Same scan acquisition, selectable averaging</p>

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Device	CIRRUS™ HD-OCT v8.0 (K150977) - Primary Predicate Device	PLEX™ Elite 9000 SS-OCT Proposed Device	Discussion
Normative Database	Retinal Nerve Fiber Layer (RNFL) Macular Optic Nerve Head (ONH) Ganglion Cell	<i>The PLEX Elite 9000 does not contain a Normative Database in Release 1.0.</i>	N/A
CIRRUS HD-OCT FUNDUS IMAGING Models 4000 & 5000		1.1.1. PLEX ELITE SS-OCT 1.1.2. FUNDUS IMAGING 1.1.3. MODEL 9000	
Methodology	Model 4000 & 5000: Line Scanning Ophthalmoscope Model 400 & 500: Live OCT fundus imaging (generate fundus image using OCT imaging system)	Line Scanning Ophthalmoscope – reuse CIRRUS Model 5000 Remains Unchanged from the Predicate Device.	Same
CIRRUS HD-OCT IRIS IMAGING		1.1.4. PLEX ELITE SS-OCT IRIS IMAGING Remains Unchanged from the Predicate Device.	1.1.5.
Methodology	CCD camera and LED illumination	CCD camera and LED illumination	Same
Live iris image	Light emitting diode (LED), 700 nm	Light emitting diode (LED), 700 nm	Same
CIRRUS HD-OCT FIXATION		1.1.6. PLEX ELITE SS-OCT FIXATION	1.1.7.
Internal fixation source	LCD (green pixels), Models 400 / 4000 LED Array, 9 positions, Models 500 / 5000	LCD (green pixels), As cleared in CIRRUS HD-OCT, Model 4000	Same as Model 4000

Clinical Evaluation

Clinical imaging performed on human eyes for each scan type supported by the PLEX Elite system is provided to demonstrate the ability of the PLEX Elite 9000 to image the posterior element with a wider field of view, increased depth penetration and with a higher signal-to-noise ratio as compared to the CIRRUS HD-OCT system.

To demonstrate the ability of the PLEX Elite 9000 angiography scans to image a range of retinal vascular pathologies affecting different anatomic depths through the retina and choroid, a clinical report is provided that includes clinical images from a case series study comparing PLEX Elite 9000 OCT angiography to FA, ICGA, CIRRUS HD-OCT angiography, and color fundus photography from subjects with varying retinal pathologies including retinal ischemia, microaneurysms, choroidal neovascularization, and retinal neovascularization. In addition, the clinical report compares PLEX Elite 9000 OCT angiography with ICGA images for lesions of the choroid, such as choroidal polyps in polypoidal choroidal vasculopathy and choroidal neovascular membranes.

The case series presented in the clinical report demonstrated the ability of the new PLEX

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Elite 9000 to produce high quality images of the retina and choroid. The PLEX Elite 9000 angiography scans were shown to image the structures of the retina and choroid as well as the predicate CIRRUS HD- OCT device.

Additionally, a literature review of peer-reviewed, journal studies were evaluated and several are provided to support the indications for use statement for the PLEX Elite 9000 SS-OCT with Software Version 1.0. The articles serve to support the clinical efficacy of the SS-OCT Laser system and to demonstrate substantial equivalence to the CIRRUS HD-OCT with software version 8.0 (K150977).

510(k) Summary (21 CFR §807.92(c))

A technological comparison and clinical testing demonstrate that the PLEX Elite 9000 SS-OCT system is functionally equivalent to the primary predicate CIRRUS HD-OCT (K150977), utilizing the similar SS Laser system of the reference predicate, the IOLMaster 700 system (K143275) and does not raise new questions regarding safety and effectiveness.

As described in this 510(k) Summary, all testing deemed necessary was conducted on the PLEX Elite 9000 SS-OCT with Software Version 1.0 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 and reference devices.