June 25, 2019

Carl Zeiss Meditec, Inc
Saurabh Jamkhindikar
Senior Regulatory Affairs Specialist
5160 Hacienda Drive
Dublin, CA 94568

Re: K191194
Trade/Device Name: Clarus
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: QER,
Dated: May 1, 2019
Received: May 3, 2019

Dear Saurabh Jamkhindikar:

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,

Bradley Cunningham
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191194

Device Name
CLARUS Model 700

Indications for Use *(Describe)*
The CLARUS 700 ophthalmic camera is indicated to capture, display, annotate and store images to aid in the diagnosis and monitoring of diseases and disorders occurring in the retina, ocular surface and visible adnexa. It provides true color and autofluorescence imaging modes for stereo, widefield, ultra-widefield, and montage fields of view.
The CLARUS 700 angiography is indicated as an aid in the visualization of vascular structures of the retina and the 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

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92), the 510(k) Summary for the CLARUS 700 with Software Version 1.1 is provided below.

GENERAL INFORMATION

Manufacturer:	Carl Zeiss Meditec, Inc. 5160 Hacienda Drive Dublin, California 94568 (925) 557-4100 (phone) (925) 557-4259 (fax) Est. Reg. No. 2918630
Contact Person:	Saurabh Jamkhindikar Senior Regulatory Affairs Specialist Carl Zeiss Meditec, Inc. 5160 Hacienda Drive Dublin, California 94568 saurabh.jamkhindikar@zeiss.com (925) 557-4696 (phone) (925) 557-4259 (fax)
Date Summary Prepared:	June 21, 2019
Classification Name:	Camera, Ophthalmic, Slit-scanning
Regulation Description:	Ophthalmic Camera (acc. 21 CFR 886.1120)
Classification:	Class II (acc. 21 CFR 886.1120)
Product Code:	QER
Common Name:	Ophthalmic Camera
Trade/Proprietary Name:	CLARUS
Model(s):	700

PREDICATE DEVICE

Company:	Carl Zeiss Meditec, Inc.
Device:	CLARUS 500 (K181444)

REFERENCE DEVICE

Company: OPTOS PLC.

Device: P200DTx - Optos California Fa (K142897)

INTENDED USE / INDICATIONS FOR USE

The CLARUS 700 ophthalmic camera is indicated to capture, display, annotate and store images to aid in the diagnosis and monitoring of diseases and disorders occurring in the retina, ocular surface and visible adnexa. It provides true color and autofluorescence imaging modes for stereo, widefield, ultra-widefield, and montage fields of view.

The CLARUS 700 angiography is indicated as an aid in the visualization of vascular structures of the retina and the choroid.

DEVICE DESCRIPTION

The CLARUS™ model 700 is a new addition to the CLARUS product family consisting of existing model 500 (K181444). The CLARUS 700 is an active, software controlled, high-resolution ophthalmic imaging device for In-vivo imaging of the human eye. Imaging modes include True color, Fundus Auto-fluorescence with green excitation, Fundus Auto-fluorescence with blue excitation, Fluorescein Angiography, Stereo and External eye. All true color images can be separated into red, green and blue channel images to help enhance visual contrast of details in certain layers of the retina. The CLARUS 700 angiography imaging aids in the visualization of the vascular structures of the retina and the choroid. With a single capture, CLARUS 700 produces a 90º high definition widefield image. Widefield images are automatically merged to achieve a 135º ultra-widefield of view. The CLARUS 700 makes use of a deep learning algorithm for Optic Nerve Head (ONH) detection. The ultra-widefield montage on CLARUS 700 is no longer dependent just on the patient accurately fixating their gaze on the internal fixation. With the ONH detection, the software will find the optic nerve and determine based on the image(s) captured where the patient was gazing at the point of capture. The CLARUS 700 device allows clinicians to easily review and compare high-quality images captured during a single exam while providing annotation and caliper measurement tools that allow in-depth analysis of eye health. CLARUS 700 is designed to optimize each patient's experience by providing a simple head and chin rest that allows the patient to maintain a stable, neutral position while the operator brings the optics to the patient, facilitating a more comfortable imaging experience. The ability to swivel the device between the right and left eye helps technicians capture an image without realigning the patient. Live IR Preview allows the technician to confirm image quality and screen for lid and lash obstructions, prior to imaging, ensuring fewer image recaptures.

The CLARUS 700 device's principle of operation is Slit Scanning Ophthalmic Camera also referred to as Broad Line Fundus Imaging (BLFI), same as the predicate CLARUS 500 (K181444). During image capture, a line of illumination passes through the slit and scans across the retina. A 2D monochromatic camera captures the returned light to image the retina. A single sweep of the

illumination is used to illuminate the retina for image capture. Repeated sweeps of near infrared light are used for a live retina view for alignment. Red, green and blue LEDs sequentially illuminate to generate true color images. Blue and green LED illumination enables Fundus Autofluorescence (FAF) imaging. Fluorescein Angiography images are captured with green LED illumination at a wavelength that stimulates fluorescence of the injected sodium fluorescein dye.

The CLARUS 700 system is mainly comprised of an acquisition device, all-in-one PC, keyboard, mouse, instrument lift table and external power supply.

The CLARUS 700 hardware is based off the predicate CLARUS 500 (K181444) hardware. New FA imaging mode on the CLARUS 700 require the below hardware changes:

- Added filters to support FA imaging mode
- Updated slim turret and motor with new positions for reliability, angiography filters and FPGA code
- Updated calibration tool for new turret positions and differentiation
- Change to lightbox board for reliability and support higher duty cycle in support of FA imaging
- Updated Onyx All-in-one Computer for 32GB RAM and 2TB HDD storage space
- Updated belt driven slit for reliability and to support FA imaging mode
- Updated camera to support FA imaging mode

The CLARUS software provides the user the capability to align, capture, review and annotate images. The software has two installation configurations: Software installed on the Instrument (Acquisition & Review) as well as Software installed on a separate 'Review Station' (Laptop or Computer) (only Review).

The CLARUS software version 1.1 is based off the predicate CLARUS software version 1.0 (K181444). Added image capture modality includes Fluorescein Angiography. Other changes implemented in the software version 1.1 include:

- Automated Optic Nerve Head (ONH) detection for montaging
- Smart (Region of Interest) Focus
- Auto brightness for FA image series
- Calibration software update for DEVICE hardware changes
- FORUM/ Other EMR connectivity updates for new FA imaging mode

The CLARUS 700 device meets the requirements of ISO 10940:2009 standard. The device technical specifications are identical to the predicate device. The performance specifications relevant to the user are summarized in the Table 1 below.

Table 1 – Specifications

Feature	Specification
FoV – Widefield (single capture)	• 90º
FoV – Ultra-widefield (montage)	• 135º
Image Resolution	• 60 lp/mm at central field (0°) • 40 lp/mm at 23° FOV • 25 lp/mm at 45° FOV
Sensors	• 12-megapixel monochrome
Sensor Resolution	• 3000 x 3000 pixels
Focusing Range	• +20 D to -24D
Pixel Pitch on the Fundus	• 7.3 µm/pixel

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.

BIOCOMPATIBILITY

The CLARUS 700 has two patient-contact components, i.e. the patient chin rest and the forehead rest, which are surface contacting and have transient contact. The device uses the same patient contacting materials as used in the predicate device. The materials have been evaluated for Biocompatibility and comply with requirements of ISO 10993-1:2009 standard.

PERFORMANCE DATA & SUMMARY OF VERIFICATION AND VALIDATION ACTIVITY

The following performance testing for the CLARUS 700 is provided to support the substantial equivalence of the subject device:

Design Verification Testing

The design verification testing results demonstrate that the system complies with the established system requirements.

Design Validation Testing

The purpose of the design validation testing is to measure customer acceptance of the intended use, features and the workflow. The validation results demonstrate that the device meets the requirements set out by the Product Requirements Specifications and all aspects of the user experience met the acceptance criteria.

Testing to Consensus Standards

The device was 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.

Electrical Safety Testing

The electrical safety for the device has been evaluated and was found to be in compliance with the ANSI AAMI 60601-1:2005/(R) 2012 and A1:2012 (Ed 3.1) standard.

Electromagnetic Compatibility Testing

The electromagnetic compatibility (EMC) for the device has been evaluated and was found to be in compliance with the IEC 60601-1-2:2014 Ed 4.0 standard.

Optical Safety

The same optical pathway is used in both the CLARUS 700 device and the predicate. The device includes additional filters in the optical pathway for Fluorescein Angiography imaging modality.

The optical safety of the device for Fluorescein Angiography imaging mode with recognized consensus standard ANSI Z80.36-2016 and ISO 15004-2:2007 has been demonstrated by performing hazard analysis assessment. The device is determined to be a Group 1 instrument.

There are no changes to the design or use of the near Infrared laser for CLARUS 700 from the predicate device. The classification and safety of the device's laser components in accordance with the recognized consensus standard IEC 60825-1:2007 has been established. The device is determined to be a Class 1 laser system.

Environmental Conditions

There are no significant hardware or requirement changes for the CLARUS 700 device from the predicate device requiring re-testing for environmental conditions. The device complies with the requirements for environmental conditions for use, storage and transport as specified in the ISO 15004-1:2009 standard.

Software Verification:

Software verification testing for the device was conducted and documentation is provided as recommended by the FDA's Guidance for Industry and FDA staff, "Guidance for the Content of premarket Submissions for Software Contained in Medical Devices."

DICOM Conformity Assessment

The device complies with the NEMA PS 3.1-3.20 (2016) standard and a DICOM Conformance Statement is provided.

CLINICAL TESTING

A non-significant risk clinical study was completed with the CLARUS 700 to support indications for use statement for the product. The objective of this study was to demonstrate the ability of the CLARUS 700 device in capturing fluorescein angiography (FA) images of the retina and choroid in a range of vitreoretinal and choroidal diseases. The study also included comparison data obtained on a reference device Optos California Fa (K142897) during the same angiogram procedure in some cases.

As part of this study, 20 eyes from 13 subjects (11 male, 2 female) were enrolled and imaged. The average age of the recruited subjects was 62 years old. Overall, Fluorescein Angiography images acquired on the CLARUS 700 device showed good clinical utility. The passing rate was as below.

Criteria#	Criteria Description	Passing Rate
1	Area and lesion of interest is visible on the angiogram	17/20 (85%)
2	Clinically useful image. Image appearance is consistent with the disease and transit phase of dye	19/20 (95%)
3	Artifacts, if any, do not interfere with ability to interpret image	19/20 (95%)

The clinical study results demonstrate the ability of CLARUS 700 to capture clinically useful Fluorescein Angiography images of the retina and choroid in a range of vitreoretinal and choroidal diseases. In addition, the wide field of view allows more retinal area to be imaged at once, making it possible to capture the entire posterior pole during the early phase of dye transit, and reducing the number of peripheral sweeps needed during the later phases to cover the retina. This may be useful in documenting diseases that affect large parts of the retina, or diseases that affect the retina outside the posterior pole, such as diabetic retinopathy, retinal vein and artery occlusions.

SUBSTANTIAL EQUIVALENCE DISCUSSION

The predicate device is Carl Zeiss Meditec, Inc's CLARUS model 500 (K181444). The intended use of both devices is the same. They are both used to capture, display, store, annotate and review images of the human retina and the surrounding parts of the eye under mydriatic and non-mydriatic conditions. Both devices support the diagnosis and monitoring of eye diseases.

The differences in the Indications for Use statement for the devices do not affect their intended use, anatomical site of application or target population.

The technological characteristics of both the devices are identical. Both devices use the Slit

Scanning Ophthalmoscope technique (also referred to as Broad Line Fundus Imaging (BLFI)). Both devices have the same basic functions for capturing, displaying, storing and reviewing images of the human retina and surrounding parts of the eye. Both devices provide a wide field of view (FoV) of 90º with a single capture. Both devices have an identical patient-operator interface and controls for operating the device. With both devices, an external monitor is used to view images. For both devices, the software provides image review functionality.

Both devices use the same light sources to illuminate the retinal area and digital image sensors for recording images. Both devices provide retinal imaging modes under non-mydriatic and mydriatic conditions.

The CLARUS 700 provides Fluorescein Angiography imaging mode not available in the predicate. Fluorescein Angiography fundus imaging is a well-established imaging modality and has been widely used by eye care professionals in documenting various ocular diseases and conditions. Design Verification testing was completed to demonstrate that the specified Fluorescein Angiography imaging mode is provided and confirmed. A clinical study was completed to demonstrate the ability of the CLARUS 700 device to capture clinically useful Fluorescein Angiography images of the retina and choroid in a range of vitreoretinal and choroidal diseases. The study also includes comparison data obtained on a reference device during the same angiogram procedure for some of the cases.

A comparison of the subject device to the predicate device is provided in Table 2.

Table 2: Comparison Table of Proposed Device CLARUS 700 with SW Version 1.1 and Predicate CLARUS 500 with SW Version 1.0 (K181444)

Device Characteristics	**CLARUS Model 700 with SW version 1.1 (K191194) – Proposed Device**	**CLARUS Model 500 with SW version 1.0 (K181444) – Predicate Device**
Manufacturer	Carl Zeiss Meditec, Inc. 5160 Hacienda Drive Dublin, CA 94568, USA	Carl Zeiss Meditec, Inc. 5160 Hacienda Drive Dublin, CA 94568, USA
510(k)	• K191194	• K181444
Proprietary Name	• CLARUS model 700	• CLARUS model 500
Device Classification Name	• Camera, Ophthalmic, Slit-Scanning	• Camera, Ophthalmic, Slit-Scanning
Generic/ Common Name	• Ophthalmic camera	• Ophthalmic camera
Product Code	• QER	• QER
Regulation Number	• 886.1120	• 886.1120

Device Characteristics	**CLARUS Model 700 with SW version 1.1 (K191194) – Proposed Device**	**CLARUS Model 500 with SW version 1.0 (K181444) – Predicate Device**
Class	• II	• II
Review Panel	• Ophthalmic	• Ophthalmic
Intended Use/ Indications for Use	The CLARUS 700 ophthalmic camera is indicated to capture, display, annotate and store images to aid in the diagnosis and monitoring of diseases and disorders occurring in the retina, ocular surface and visible adnexa. It provides true color and autofluorescence imaging modes for stereo, widefield, ultra-widefield, and montage fields of view. **The CLARUS 700 angiography is indicated as an aid in the visualization of vascular structures of the retina and the choroid.**	The CLARUS 500 ophthalmic camera is indicated to capture, display, annotate and store images to aid in the diagnosis and monitoring of diseases and disorders occurring in the retina, ocular surface and visible adnexa. It provides true color and autofluorescence imaging modes for stereo, widefield, ultra-widefield, and montage fields of view.
Target Population	• Opticians • Ophthalmic Photographers • Optometrists • Ophthalmologists • Medical Assistants • Clinical Researchers	• Opticians • Ophthalmic Photographers • Optometrists • Ophthalmologists • Medical Assistants • Clinical Researchers
Anatomical Site	• Retina, ocular surface and visible adnexa	• Retina, ocular surface and visible adnexa
Device Type	• Fundus Camera	• Fundus Camera
Methodology	• Slit Scanning Ophthalmoscope, also referred to as Broad Line Fundus Imaging (BLFI)	• Slit Scanning Ophthalmoscope, also referred to as Broad Line Fundus Imaging (BLFI)
Principle of Fundus Image Capturing	• Broad Line Fundus Imaging (BLFI) using LEDs and laser illumination • Near-IR laser illumination for live retina preview • LEDs (red, green, blue) used for true color, fundus autofluorescence and **fluorescein angiography** imaging modes • Live preview and image-capture with 12-megapixel monochrome sensors	• Broad Line Fundus Imaging (BLFI) using LEDs and laser illumination • Near-IR laser illumination for live retina preview • LEDs (red, green, blue) used for true color and fundus autofluorescence imaging modes • Live preview and image-capture with 12-megapixel monochrome sensors

Device Characteristics	**CLARUS Model 700 with SW version 1.1 (K191194) – Proposed Device**	**CLARUS Model 500 with SW version 1.0 (K181444) – Predicate Device**
Image Capture Modes	• True color (with red, green and blue channel separation in review mode) • Fundus autofluorescence with green excitation • Fundus autofluorescence with blue excitation • **Fluorescein Angiography** • Stereo • External	• True color (with red, green and blue channel separation in review mode) • Fundus autofluorescence with green excitation • Fundus autofluorescence with blue excitation • Stereo • External
Illumination Source for Image Acquisition	• Red LED: 585-640 nm • Green LED: 500-585 nm • Blue LED: 435-500 nm • Near-infrared laser diode: 785 nm	• Red LED: 585-640 nm • Green LED: 500-585 nm • Blue LED: 435-500 nm • Near-infrared laser diode: 785 nm
Laser Class (Based on IEC 60825-1:2007)	• Class 1	• Class 1
Device Group (Optical safety)	• Group 1 (ANSI Z80.36-2016)	• Group 1 (ANSI Z80.36-2016)
Illumination Source for Live Preview	• Near-infrared laser diode: 785 nm	• Near-infrared laser diode: 785 nm
Detector Type	• Internal CMOS sensors – 12 megapixels	• Internal CMOS sensors – 12 megapixels
Filters	• Barrier and Excitation Filters for Fundus Autofluorescence Blue • Barrier and Excitation Filters for Fundus Autofluorescence Green • **Barrier and Excitation Filters for Fluorescein Angiography**	• Barrier and Excitation Filters for Fundus Autofluorescence Blue • Barrier and Excitation Filters for Fundus Autofluorescence Green
Field of View	• 90° (widefield - single shot image) • 135° (ultra-widefield – two shot auto montage)	• 90° (widefield - single shot image) • 135° (ultra-widefield – two shot auto montage)
Refractive Error Compensation	• +24 D…. -20 D, continuous	• +24 D…. -20 D, continuous
Minimum pupil size	• 2.5 mm	• 2.5 mm
Working Distance	• 25 mm (patient's eye – front lens)	• 25 mm (patient's eye – front lens)

Device Characteristics	**CLARUS Model 700 with SW version 1.1 (K191194) – Proposed Device**	**CLARUS Model 500 with SW version 1.0 (K181444) – Predicate Device**
Fixation Target	• Internal and External	• Internal and External
Configuration	• Acquisition unit consists of the acquisition head (includes image acquisition optics), cross-table and the patient support • Peripheral components include the All-in-One PC, keyboard, mouse and the instrument lift table	• Acquisition unit consists of the acquisition head (includes image acquisition optics), cross-table and the patient support • Peripheral components include the All-in-One PC, keyboard, mouse and the instrument lift table
System Control Input Devices	• Joystick for operating image acquisition head • Keyboard/Touchpad/Mouse for operating internal computer	• Joystick for operating image acquisition head • Keyboard/Touchpad/Mouse for operating internal computer
Patient Contacting Materials	• Chin rest and forehead rest	• Chin rest and forehead rest
Materials – Patient Contact	• Chin rest and forehead rest - ABS/PC Alloy, Bayer Bay Blend #FR3010, Color – Medium Gray RAL-U713	• Chin rest and forehead rest - ABS/PC Alloy, Bayer Bay Blend #FR3010, Color – Medium Gray RAL-U713
Operating System	• Microsoft Windows 10 I0T Enterprise Version 64 bit	• Microsoft Windows 10 I0T Enterprise Version 64 bit
Display Types	• 22” Full HD MVA LCD with LED Backlight (external)	• 22” Full HD MVA LCD with LED Backlight (external)
Data Storage	• 2 TB (At-Instrument Computer)	• 1 TB (At-Instrument Computer)
Export	• Via FORUM/PACS, DICOM, network drive and USB thumb drives	• Via FORUM, DICOM, network drive and USB thumb drives
Software Features	• Review and Analysis of Fundus Images	• Review and Analysis of Fundus Images
Electrical Requirements	• Input Voltage: 100-240 V~, 50/60 Hz, 4A max • Power consumption: Max. 1315 VA for DEVICE and lift table configuration (standalone DEVICE not available)	• Input Voltage: 100-240 V~, 50/60 Hz, 4A max • Power consumption: Max. 1315 VA for DEVICE and lift table configuration (standalone DEVICE not available)

Device Characteristics	**CLARUS Model 700 with SW version 1.1 (K191194) – Proposed Device**	**CLARUS Model 500 with SW version 1.0 (K181444) – Predicate Device**
Electrical Safety parameters	• Protection Class: 1 • Device Type (IEC 60601-1): B • Enclosure Protection: IPX0 (No degree of protection against ingress of water or particulate matter)	• Protection Class: 1 • Device Type (IEC 60601-1): B • Enclosure Protection: IPX0 (No degree of protection against ingress of water or particulate matter)
Environmental Conditions: Operation	• Temperature: +10° to +35° C • Relative Humidity: 30% to 90% (excluding condensation) • Atmospheric Pressure: 800 hPa to 1060 hPa	• Temperature: +10° to +35° C • Relative Humidity: 30% to 90% (excluding condensation) • Atmospheric Pressure: 800 hPa to 1060 hPa
Environmental Conditions: Storage	• Temp. -10° to +55° C • Relative Humidity 10% to 95% (excluding condensation) • Atmospheric Pressure 700 hPa to 1060 hPa	• Temp. -10° to +55° C • Relative Humidity 10% to 95% (excluding condensation) • Atmospheric Pressure 700 hPa to 1060 hPa
Environmental Conditions: Transport	• Temp. -40° to +70° C • Relative Humidity 10% to 95% (excluding condensation) • Atmospheric Pressure 500 hPa to 1060 hPa	• Temp. -40° to +70° C • Relative Humidity 10% to 95% (excluding condensation) • Atmospheric Pressure 500 hPa to 1060 hPa

A comparison of the subject device to the reference device Optos California fa is provided in Table 3. The reference device Optos California fa is used to claim equivalence for Fluorescein Angiography imaging mode in CLARUS 700.

Table 3: Comparison Table of Proposed Device CLARUS 700 with SW Version 1.0 and Reference device Optos California fa (K142897)

Device Characteristics	**CLARUS Model 700 with SW version 1.1 (K191194) – Proposed Device**	**Optos California P200DTx (K142897) - Reference Device**
Manufacturer	Carl Zeiss Meditec, Inc. 5160 Hacienda Drive Dublin, CA 94568, USA	OPTOS PLC. QUEENSFERRY HOUSE, CARNEGIE BUSINESS CAMPUS Dunfermline, GB Ky11 8gr
510(k)	• K191194	• K142897
Proprietary Name	• CLARUS model 700	• Optos California fa

Device Characteristics	**CLARUS Model 700 with SW version 1.1 (K191194) – Proposed Device**	**Optos California P200DTx (K142897) - Reference Device**
Device Classification Name	• Camera, Ophthalmic, Slit-Scanning	• Ophthalmoscope, Laser, Scanning
Generic/ Common Name	• Ophthalmic camera	• Ophthalmoscope
Product Code	• QER	• MYC
Regulation Number	• 886.1120	• 886.1570
Class	• II	• II
Review Panel	• Ophthalmic	• Ophthalmic
Intended Use/ Indications for Use	The CLARUS 700 ophthalmic camera is indicated to capture, display, annotate and store images to aid in the diagnosis and monitoring of diseases and disorders occurring in the retina, ocular surface and visible adnexa. It provides true color and autofluorescence imaging modes for stereo, widefield, ultra-widefield, and montage fields of view. **The CLARUS 700 angiography is indicated as an aid in the visualization of vascular structures of the retina and the choroid.**	The P200DTx scanning laser ophthalmoscope is indicated for use as a widefield and retinal fluorescence and autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases and disorders that manifest in the retina. It is also indicated for use as a widefield scanning laser ophthalmoscope for viewing choroidal circulation patterns that are illuminated using Indocyanine Green dye and for aiding in both the assessment of choroidal circulation and in the diagnosis of choroiditis or choroidal diseases.
Methodology	• Slit Scanning Ophthalmoscope also referred to as Broad Line Fundus Imaging (BLFI)	• Scanning Laser Ophthalmoscope
Fundus Image Capture Modes	• True color (with red, green and blue channel separation in review mode) • Fundus autofluorescence with green excitation • Fundus autofluorescence with blue excitation • **Fluorescein Angiography** • Stereo • External	• optomap color - Color composite view - Green laser view - Red laser view • optomap af autofluorescence • **optomap fa fluorescein angiography**

Device Characteristics	**CLARUS Model 700 with SW version 1.1 (K191194) – Proposed Device**	**Optos California P200DTx (K142897) - Reference Device**
Illumination Source for Image Acquisition	• Red LED: 585-640 nm • Green LED: 500-585 nm • Blue LED: 435-500 nm • Near Infrared laser diode: 785 nm	• Red laser: 635 nm • Green laser: 532 nm • Blue laser: 488 nm
Field of View	• 90° (widefield - single shot image) • 135° (ultra-widefield – two shot auto-montage)	• 148° x 115° (angular FoV – external to eye)

CONCLUSION

The intended use for the device CLARUS 700 and the predicate CLARUS 500 (K181444) is the same. They are both used to capture, display, annotate, store and review images of the human retina and the surrounding parts of the eye under mydriatic and non-mydriatic conditions. Both devices support the diagnosis and monitoring of eye diseases.

The technological characteristics of both the devices are identical. Both devices use the Slit Scanning Ophthalmoscope technique (also referred to as Broad Line Fundus Imaging (BLFI) in this premarket notification). Overall, both devices have the same functions for capturing, displaying, storing and reviewing images of the human retina and surrounding parts of the eye.

The CLARUS 700 device provides Fluorescein Angiography fundus imaging mode not available in the predicate. Design Verification testing was completed to demonstrate that the specified Fluorescein Angiography imaging mode is provided and confirmed. In addition, a clinical study was completed to demonstrate the ability of the CLARUS 700 device to capture clinically useful Fluorescein Angiography images of the retina and choroid in a range of vitreoretinal and choroidal diseases. The study also includes comparison data obtained on the reference Optos California Fa (K142897) during the same angiogram procedure in same cases.
Performance data is provided to demonstrate that the CLARUS 700 device can achieve its intended use. Bench testing (including software and electrical safety/ EMC safety), biocompatibility and clinical data all support that the CLARUS 700 device is as safe and effective as the predicate device and is therefore considered substantially equivalent to the predicate device.

510(K) SUMMARY

Based on the successful Design Verification & Validation testing, it is Carl Zeiss Meditec, Inc.'s opinion that the CLARUS 700 does not introduce any new potential safety risks and is substantially equivalent to, and performs as well as, the predicate device.

Additionally, all testing deemed necessary was conducted on the CLARUS 700 to ensure that the device is as safe and effective as the predicate device when used in accordance with its Instructions for Use.