January 10, 2019

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

Re: K181444
Trade/Device Name: Clarus
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: QER
Dated: November 28, 2018
Received: November 30, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

Bradley S. Cunningham -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181444

Device Name
CLARUS Model 500

Indications for Use *(Describe)*
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.

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 500 with Software Version 1.0 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:	January 09, 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
Trade/Proprietary Name:	CLARUS
Model(s):	500

PREDICATE DEVICE

Company:	Carl Zeiss Meditec AG
Device:	VISUCAM PRO NM (K052268)

REFERENCE DEVICE

Company:	Carl Zeiss Meditec AG
Device:	CIRRUS photo Model 600 (K133217)

INTENDED USE / INDICATIONS FOR USE

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.

DEVICE DESCRIPTION

The CLARUS™ 500 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, 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. With a single capture, CLARUS 500 produces a 90º high definition widefield image. Widefield images are automatically merged to achieve a 135º ultra-widefield view. The technology allows clinicians to easily review and compare high-quality images captured during a single exam while providing annotation and caliper measurement tools that allow analysis of eye health. CLARUS 500 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 Infrared Preview allows the technician to confirm image quality and screen for lid and lash obstructions, prior to imaging, ensuring fewer image recaptures.

The CLARUS 500 device's principle of operation is based on Slit Scanning Ophthalmoscope also referred to as Broad Line Fundus Imaging (BLFI). During image capture, a broad line of illumination is scanned across the retina. A 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.

The CLARUS 500 system is mainly comprised of an acquisition device, all-in-one PC, keyboard, mouse, instrument lift table and external power supply.

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 500 technical features relevant to the user are: Field of View (FoV), Image Resolution, Pixel Pitch and Focusing Range. The device meets the requirements of ISO 10940:2009 standard. The performance specifications 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 500 has two patient-contact components, i.e. the patient chin rest and the forehead rest, which are surface contacting and have transient contact. 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

CLARUS 500 meets the requirements of ISO 10940:2009 standard for fundus cameras. The performance of widefield imaging mode in CLARUS 500 is verified through bench testing using a test eye. The performance of ultra-widefield montage in CLARUS 500 is verified through software algorithm verification.

The following performance testing for the CLARUS 500 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 optical safety of the device 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.

The 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

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 clinical study was conducted to demonstrate the performance of the CLARUS 500 imaging modes as compared to the reference device. Study results concluded that similar amount of clinical features can be resolved on CLARUS 500 images as the images from the reference device in almost all cases. In addition, the wide field of view of the CLARUS 500 image allows more retinal area to be viewed in a single image.

SUBSTANTIAL EQUIVALENCE DISCUSSION

The predicate device is VISUCAM PRO NM (K052268). The intended use of both devices is the same. They are both used to capture, display, 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 differences in the Indications for Use statement for the devices do not affect their intended use, anatomical site of application or target population.

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 utilize a standard slit lamp-joystick mechanism. Both devices have a similar 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.

The CLARUS 500 provides a wide field of view (FoV) of 90º with a single capture, whereas the predicate provides traditional FoV of 30º and 45º. The different specifications for FoV does not impact safety. The predicate device also provides for a wider field of view in the Panorama (montage) mode. Design Verification activities demonstrate that the device specifications for a wider FoV were met.

Both devices use the Ophthalmoscope principle of modern AC-powered digital ophthalmic cameras for imaging. Both devices provide retinal imaging modes under non-mydriatic and mydriatic conditions. Both devices use an internal light source to illuminate the retinal area and digital image sensors for recording images.

The devices differ in the specifics of how they illuminate and image the retina and the ocular surface. The CLARUS 500 uses the Slit Scanning Ophthalmoscope technique (also referred to as Broad Line Fundus Imaging (BLFI)). The predicate uses a more conventional flash photography illumination technique for retinal imaging. The Slit Scanning technique used in the device is very similar to the Line Scanning Ophthalmoscope technique used in currently marketed retinal cameras. The CLARUS 500 uses LEDs and near-infrared lasers for illumination, whereas the predicate uses a visible xenon flash lamp. The questions associated with these characteristics,

however, are typical questions for ophthalmic imaging systems. Performance data is therefore provided to demonstrate that the device can achieve its intended use and is safe for the patient and the operator.

The CLARUS 500 provides Fundus Autofluorescence imaging: FAF-Blue and FAF-Green, not available in the predicate. FAF retinal imaging modality has been used in clinical practice for a number of years and is a proven method in retinal diagnosis. Design Verification testing was completed to demonstrate that the specified FAF imaging modes are provided and confirmed. A clinical study was performed to demonstrate the performance of the FAF-B and FAF-G imaging modes as compared to the FAF imaging mode of the reference device CIRRUS photo.

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

Table 2: Comparison Table of Proposed Device CLARUS 500 with Software Version 1.0 and Predicate VISUCAM PRO NM (K052268)

Device Characteristics	**CLARUS Model 500 with SW version 1.0 – Proposed Device**	**VISUCAM PRO NM (K052268) – Predicate Device**
Manufacturer	Carl Zeiss Meditec, Inc. 5160 Hacienda Drive Dublin, CA 94568, USA	Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 D-07745 Jena, Germany
510(k)	• K181444	• K052268
Proprietary Name	• CLARUS model 500	• VISUCAM PRO NM
Device Classification Name	• Camera, Ophthalmic, Slit-scanning	• Camera, Ophthalmic, Ac-Powered
Generic/ Common Name	• Ophthalmic camera	• Ophthalmic camera
Product Code	• QER	• HKI
Regulation Number	• 886.1120	• 886.1120
Class	• II	• II
Review Panel	• Ophthalmic	• Ophthalmic

Device Characteristics	CLARUS Model 500 with SW version 1.0 – Proposed Device	VISUCAM PRO NM (K052268) – Predicate Device
Intended Use/ Indications for Use	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.	The VISUCAMTM PRO NM Digital Camera is suitable for photographing, displaying and storing the data of the retina and surrounding parts of the eye to be examined under mydriatic and non-mydriatic conditions. These photographs support the diagnosis and subsequent observation of eye diseases which can be visually monitored and photographically documented.
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 and surrounding parts of the eye
Device Type	• Fundus Camera	• Fundus Camera Main Unit
Methodology	• Slit Scanning Ophthalmoscope	• Ophthalmoscope (Fundus Imaging)
Principle of Fundus Image Capturing	• Broad Line Fundus Imaging (BLFI) using LEDs and laser illumination • Near-IR laser illumination for live retina preview • LEDs used for true color, and fundus autofluorescence imaging modes • Live preview and image-capture with 12 megapixel monochrome sensors	• Short pulse flash lamp illumination for taking fundus image (photographs) • Continuous IR-LED-illumination for live retina observation • Xenon flash lamp used as illumination source for all imaging modes • Live observation and image-capture with CCD-sensor
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 • Stereo • External	• Color • Green • Red • Blue • Stereo • Panorama (Montage) • External

Device Characteristics	CLARUS Model 500 with SW version 1.0 – Proposed Device	VISUCAM PRO NM (K052268) – Predicate Device
Detector Type	• Internal CMOS sensors – 12 megapixels	• Internal CCD camera – 5.0 megapixels
Field of View	• 90° (widefield - single shot image) • 135° (ultra-widefield – two shot auto montage)	• 45° and 30°
Refractive Error Compensation	• +24 D…. -20 D, continuous	• +35 D…. -35 D, continuous
Minimum pupil size	• 2.5 mm	• 4.0 mm; 3.3 mm (small pupil mode)
Working Distance	• 25 mm (patient's eye – front lens)	• 40 mm (patient's eye – front lens)

A comparison of the subject device to the reference device CIRRUS photo is provided in Table 3. The reference device CIRRUS photo is used to claim equivalence for Fundus Autofluorescence imaging mode in CLARUS 500.

Table 3: Comparison Table of Proposed Device CLARUS 500 with Software Version 1.0 and Reference device CIRRUS photo (K133217)

Device Characteristics	CLARUS Model 500 with SW version 1.0 – Proposed Device	CIRRUS photo Model 600 (K133217) – Reference Device
Manufacturer	Carl Zeiss Meditec, Inc. 5160 Hacienda Drive Dublin, CA 94568, USA	Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 D-07745 Jena, Germany
510(k)	• K181444	• K133217
Device Classification Name	• Camera, Ophthalmic, Slit-scanning	• Tomography, Optical Coherence • Camera, Ophthalmic, Ac-Powered
Generic/ Common Name	• Ophthalmic camera	• Optical Coherence Tomographer (OCT) • Ophthalmic camera
Product Code	• QER	• OBO • HKI
Regulation Number	• 886.1120	• 886.1570 • 886.1120
Anatomical Site	• Retina, ocular surface and visible adnexa	• Retina and surrounding parts of the eye

Device Characteristics	CLARUS Model 500 with SW version 1.0 – Proposed Device	CIRRUS photo Model 600 (K133217) – Reference Device
Device Type	• Fundus Camera	• Fundus Camera Main Unit with Spectral Domain OCT Module (Line Scanning module)
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*** • Stereo • External	• Color • Green • Red • Blue • ***Fundus autofluorescence*** • Fluorescein angiography • Indocyanine green angiography • Stereo • External

CONCLUSION

The intended use for the CLARUS 500 and VISUCAM PRO NM is the same. They are both used to capture, display, 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.

Overall, the devices are similar in imaging modes, features and functions. There are differences in their technological characteristics. Both devices use the Ophthalmoscope principle of the modern AC-powered digital ophthalmic cameras for imaging. The devices differ in the specifics of how they illuminate and image the retina and the ocular surface. The questions associated with these characteristics, however, are typical questions for imaging systems and patient-contacting devices. Performance data is therefore provided to demonstrate the CLARUS 500 can achieve its intended use and is safe for the patient and the operator. Bench testing (including software and electrical/EMC safety) and biocompatibility all support that the proposed device is as safe and effective as the predicate, and is therefore considered substantially equivalent to the predicate VISUCAM PRO NM. In addition, a clinical study was performed to demonstrate the performance of the device imaging modes compared to the reference device in support of the differences in imaging modes and technical characteristics.

510(K) SUMMARY

Based on the successful Design Verification & Validation testing, it is Carl Zeiss Meditec, Inc.'s opinion that the CLARUS 500 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 500 to ensure that the device is as safe and effective when used in accordance with its Instructions for Use as the predicate device.