August 28, 2023

Carl Zeiss Meditec AG
℅ Aditya Rao
Regulatory Affairs Specialist - USA
Carl Zeiss Meditec Inc
5300 Central Parkway
Dublin, California 94568

Re: K231676
Trade/Device Name: CALLISTO eye
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: NFJ
Dated: June 8, 2023
Received: June 9, 2023

Dear Aditya Rao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elvin Y. Ng -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

510(k) Number *(if known)*

K231676

Device Name

CALLISTO eye

Indications for Use *(Describe)*

CALLISTO eye Software is a software device intended for remote control of ophthalmic surgical microscopes of OPMI Lumera family and RESCAN 700, and display images of the anterior and posterior segment of the eye.

CALLISTO eye Software is indicated as graphical guidance aid to insert, align, position, and register an intraocular lens (IOL) including toric IOLs, limbal relaxing incisions, and capsulorhexis during anterior segment surgical procedures.

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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In accordance with 21 CFR 807.92 the 510(k) Summary for the CALLISTO eye is provided below.

1. SUBMITTER

Applicant: Carl Zeiss Meditec AG
Goeschwizer Strasse 51-52
D-07745 Jena
Germany

Primary Correspondent Aditya Rao
Regulatory Affairs Specialist - USA
Carl Zeiss Meditec, Inc.
5300 Central Parkway | Dublin, CA 94568
(925) 549-9579 Phone | (925) 557-4259 Fax
E-mail: aditya.rao@zeiss.com (preferred)

Date Prepared: August 15, 2023

2. DEVICE

Device Trade Name:	CALLISTO eye (Software Version 3.7.2)
Classification:	21CFR892.2050 Picture archiving and communications system
Regulatory Class:	II
Product Code:	NFJ

3. PREDICATE DEVICE

Predicate Device:	CALLISTO eye (Software Version 3.6) - K180858
Classification:	21CFR892.2050 Picture archiving and communications system
Regulatory Class:	II
Product Code:	NFJ

4. DEVICE DESCRIPTION

CALLISTO eye software operates as an adjunct to the ZEISS's family of ophthalmic surgical microscopes to process surgery videos and OCT data (B-Scan images). Specifically, the subject device has the functionality to be connected to an OCT camera (such as in RESCAN 700 (K180229)), a phaco machine (such as in QUATERA 700 (K212241), as well as MIMPS (such as FORUM (K213527).

CALLISTO eye Software must be installed on a computer with a touchscreen; this Panel PC (ORPC) is offered as an accessory. The current model of the ORPC is the CALLISTO eye Panel PC Model II. OPRC function and configuration has been modified since the last CALLISTO eye 510(k) by upgrading electronics components to accommodate lifecycle management needs.

CALLISTO eye 3.7.2 has the same functionalities as CALLISTO eye 3.6 (K180858). These functionalities include patient data management and transmission via DICOM protocol, interfaces to ZEISS's ophthalmic microscopes with/without OCT camera (RESCAN 700) and assists with overlay function for markerless marking to support IOL alignment.

Additional functionalities unique to CALLISTO eye 3.7.2 are inclusion of changes occurring from software version 3.6 to 3.7.1 and additional support of language packages, bug fixes, cybersecurity enhancements and interoperability abilities with a phaco system (QUATERA 700).

The subject device, CALLISTO eye 3.7.2, provides connectivity to the following surgical microscopes from ZEISS:

- OPMI LUMERA 700 with Integrated Data Injection System (IDIS)
- OPMI LUMERA T with External Data Injection System (EDIS)
- OPMI LUMERA I with External Data Injection System (EDIS)
- OPMI LUMERA 700 with OCT camera (RESCAN700)
- ARTEVO 800 with 3D monitor cart (3DIS)
- ARTEVO 800 with OCT camera (RESCAN700)

The software can acquire photo and videos from all surgical microscope listed above and can remote control these microscopes apart from the OPMI LUMERA T and I.
All OPMI LUMERA family surgical microscopes have been covered by the predicate device CALLISTO eye 3.6 (K180858). With the subject device the range of supported surgical microscopes was extended to the ARTEVO 800 with and without RESCAN700 as principal successor of the OPMI LUMERA 700.

The intended use and indications for use of OPMI LUMERA and ARTEVO 800 are identical and the microscopes can be applied for the same surgical procedure.

CALLISTO eye allows the connection and remote control of a surgical microscope with or without OCT Camera and thus operates as an adjunct to the family of ZEISS surgical microscopes. Functionalities such as light intensity, camera parameters, start/stop recording, zoom, focus, diaphragm, start/stop OCT scanning, etc. of the surgical microscope, including the configuration of the foot control panel and handgrips, can be accessed and managed by the user in CALLISTO eye.

CALLISTO eye Software is an assistance, information, and documentation system to support ophthalmic surgical procedures. It provides an interface to other devices to facilitate the:

- Display and recording of video data provided by ZEISS surgical microscopes (OPMI)
- Display of assistance functions (graphical guidance templates) and device information (cockpits) to aid the surgeon in the implantation of intra ocular lenses; e.g., used for the alignment for toric intraocular lenses.
- Display and recording of OCT image data provided by ZEISS RESCAN 700
- Display and exchange data with the ZEISS QUATERA 700 phacoemulsification and vitrectomy system
- Retrieval and storage of patient data from and to the FORUM MIMPS system
- Configuration of ZEISS surgical microscopes, including the assignment of functions to OPMI handgrips and foot control panel

5. INTENDED USE/INDICATIONS FOR USE

The intended use statement for the subject device is as follows:

CALLISTO eye is intended for use by trained clinical personnel. For Prescription Use ONLY.

The Indications for Use (IFU) statement for the subject device is as follows:

CALLISTO eye Software is a software device intended for remote control of ophthalmic surgical microscopes of OPMI Lumera family and RESCAN 700, and display images of the anterior and posterior segment of the eye.

CALLISTO eye Software is indicated as graphical guidance aid to insert, align, position, and register an intraocular lens (IOL) including toric IOLs, limbal relaxing incisions, and capsulorhexis during anterior segment surgical procedures.

SUBSTANTIAL EQUIVALENCE

6.1. Primary Predicate

Table 1. Subject to Predicate Device Comparison Table – Indications for Use

CALLISTO eye (Version 3.7.2) Proposed Device	CALLISTO eye (Version 3.6) Predicate (K180858)	Equivalency Analysis
CALLISTO eye Software is an assistance system that provides non-diagnostic video documentation and image capture for ophthalmic surgeries. The system allows the remote control of the surgical microscope and RESCAN 700.	CALLISTO eye Software is an assistance system that provides non-diagnostic video documentation and image capture for ophthalmic surgeries. The system allows the remote control of the surgical microscope and RESCAN 700.	Identical
The assistance system relays data of connected devices and provide this information to the surgeon. It visualizes the anterior and posterior segment image data of the eye in combination with a surgical microscope and RESCAN 700.	The assistance system relays data of connected devices and provide this information to the surgeon. It visualizes the anterior and posterior segment image data of the eye in combination with a surgical microscope and RESCAN 700.	Identical
The graphical guidance tools, as displayed on the CALLISTO eye Panel PC or microscope eyepiece, aid the surgeon to insert, align, position, and register an artificial lens. These tools are intended for anterior segment ophthalmic surgical procedures, including positioning and angular alignment of toric intraocular lenses, limbal relaxing incisions, and capsulorhexis.	The graphical guidance tools, as displayed on the CALLISTO eye Panel PC or microscope eyepiece, aid the surgeon to insert, align, position, and register an artificial lens. These tools are intended for anterior segment ophthalmic surgical procedures, including positioning and angular alignment of toric intraocular lenses, limbal relaxing incisions, and capsulorhexis.	Identical
The system utilizes surgeon information for positioning of graphical guidance tools. For	The system utilizes surgeon information for positioning of graphical guidance tools.	Identical
Rx-only / Prescription Use ONLY.	Rx-only / Prescription Use ONLY.	Identical

Table 2. Subject to Predicate Device Comparison Table – Technical Characteristics

Item	Proposed Device (This submission)	Primary Predicate Device (K180858)	Equivalency Analysis
Trade Name	CALLISTO eye	CALLISTO eye	**Identical**
Software version	CALLISTO eye Software version 3.7.2	CALLISTO eye Software version 3.6	N/A
Manufacturer	Carl Zeiss Meditec AG	Carl Zeiss Meditec AG	**Identical**
Device Classification Name	System, Image Management, Ophthalmic	System, Image Management, Ophthalmic	**Identical**
Regulation description	Medical image management and processing system	Picture archiving and communications system	**Equivalent** (Change in regulation description by FDA)
Regulation medical specialty	Radiology	Radiology	**Identical**
Review panel	Ophthalmic	Ophthalmic	**Identical**
Product code,	NFJ	NFJ	**Identical**
Regulation number	892.2050	892.2050	**Identical**
Device class	II	II	**Identical**
Indications for use	CALLISTO eye Software is a software device intended for remote control of ophthalmic surgical microscopes of OPMI Lumera family and RESCAN 700, and display images of the anterior and posterior segment of the eye. CALLISTO eye Software is indicated as graphical guidance aid to insert, align, position, and register an intraocular lens (IOL) including toric IOLs, limbal relaxing incisions, and capsulorhexis during anterior segment surgical procedures.	CALLISTO eye Software is a software device intended for remote control of ophthalmic surgical microscopes of OPMI Lumera family and RESCAN 700, and display images of the anterior and posterior segment of the eye. CALLISTO eye Software is indicated as graphical guidance aid to insert, align, position, and register an intraocular lens (IOL) including toric IOLs, limbal relaxing incisions, and capsulorhexis during anterior segment surgical procedures.	**Identical**
Applications	Ophthalmology	Ophthalmology	**Identical**
Patient Contact	No	No	**Identical**

Item	Proposed Device (This submission)	Primary Predicate Device (K180858)	Equivalency Analysis
Key components	Software only	Software only	**Identical**
Accessory	• Panel PC with touch screen and video card. • The Panel PC can be provided with a Table stand, Cart or Microscope mount	• Panel PC with touch screen and video card. • The Panel PC can be provided with a Table stand, Cart or Microscope mount	**Identical**
Hardware requirements	Minimum requirements are no longer supported. Recommended requirements: • Intel® Core i5 6442EQ 1.9GHz – 2.7GHz (Turbo mode) • 16 GB memory, • 1000 GB hard disc, Touch panel display 23.6" / 1920 x 1080	Minimum requirements: • Intel® Core i7 620M 2.66GHz, • 8 GB memory, • 500 GB hard disc, • Touch panel display 22" / 1920 x 1080 Recommended requirements: • Intel® Core i5 6442EQ 1.9GHz – 2.7GHz (Turbo mode) • 16 GB memory, • 1000 GB hard disc, Touch panel display 23.6" / 1920 x 1080	**Identical** for recommended hardware requirements. Minimum requirements are not anymore supported.
Operating system	• Microsoft Windows 10 Enterprise, 2016 LTSB 64-Bit • Oracle Java 8	• Microsoft Windows 10 Enterprise, 2016 LTSB 64-Bit • Oracle Java 8	**Identical**
Device connectivity (Supported data interfaces)	• Compatible ZEISS Surgical operating microscope • RESCAN 700 • IOLMaster 500 • IOLMaster 700[*)] • FORUM • QUATERA 700	• Surgical operating microscope (Carl Zeiss OPMI LUMERA 700, Lumera i, Lumera T) RESCAN 700 • IOLMaster 500 • IOLMaster 700[*)] • FORUM ARCHIVE & VIEWER	**Equivalent** (Addition of QUATERA 700 to device connectivity. All other data interfaces remain the identical)

Item	Proposed Device (This submission)	Primary Predicate Device (K180858)	Equivalency Analysis
Supported video cameras, video formats, and display connections/interfaces	• Digital HD camera • Video input to frame grabber card HD-SDI • Video Format: MPEG4 • 2D Video output via HDMI connection to IDIS, EDIS, and 3D monitor card.	• Digital HD camera • Video input to frame grabber card HD-SDI and S-Video)PAL, NTSC) • Video Format: MPEG2 • 2D Video output via HDMI connection to IDIS and EDIS.	**Equivalent** (Identical apart from the support for the video format and the removal of the SD camera support)
Communication protocols	• TCP/IP (LAN) o RIMS o REST • TCP/IP (WLAN) o REST via HTTPS • DICOM o REST • CAN-BUS	• TCP/IP (LAN) o RIMS o REST • TCP/IP (WLAN) o REST via HTTPS • DICOM o REST • CAN-BUS	**Identical** Note: RMI – Remote Method Invocation (Java communication protocol) REST – Representational State Transfer (programming paradigm for distributed systems)
Assistance Functions			
Support of graphical and text overlays in live video, recorded videos, images, and the eyepiece of the microscope (DIS)	Yes	Yes	**Identical**
Eye tracking	Yes	Yes	**Identical**
Reference Axis, marker-based	Yes	Yes	**Identical**
Reference Axis, markerless using reference images	Yes	Yes	**Identical**
Incisions	Yes	Yes	**Identical**
Capsulorhexis	Yes	Yes	**Identical**
Toric intraocular lens alignment (Z-Align)	Yes	Yes	**Identical**
Limbal relaxing incisions (LRI)	Yes	Yes	**Identical**
Keratoscope support (K-Track)	Yes	Yes	**Identical**
Assistance Functions for OCT support			
Remote control of	Yes	Yes	**Identical**

Item	Proposed Device (This submission)	Primary Predicate Device (K180858)	Equivalency Analysis
OCT camera RESCAN 700			
Live view of OCT scans (B-Scans)	Yes	Yes	**Identical**
Supported scan type 1-Line	Yes	Yes	**Identical**
Supported scan type 2-Line (OCT cube)	Yes	Yes	**Identical**
Supported scan type 5-Line	Yes	Yes	**Identical**
Recording of live OCT scans (OCT videos)	Yes	Yes	**Identical**
OCT Image capture	Yes	Yes	**Identical**
Capture mode for OCT cubes	Yes	Yes	**Identical**
Scan location marker overlay to indicate location, size, angle, and scan type	Yes	Yes	**Identical**
Display of OCT scans in the right eyepiece of the surgical operating microscope OPMI LUMERA 700	Yes	Yes	**Identical**
Support of single scan depth	Yes	Yes	**Identical**
Support of dual scan depth (2.9 and 5.8 mm).	Yes	Yes	**Identical**
Automatic combination of scan length and scan depth (user configurable).	Yes	Yes	**Identical**
OCT XY-tracking	Yes	Yes	**Identical**
OCT Z tracking	Yes	Yes	**Identical**
Support of a fundus viewing system	Yes Non-contact type (Zeiss RESIGHT) Contact type (e.g., contact glass, aka vitrectomy contact lens)	Yes Non-contact type (Zeiss RESIGHT) Contact type (e.g., contact glass, aka vitrectomy contact lens)	**Identical**
Documentation and Data Management Capabilities			
User management	Yes	Yes	**Identical**
Patient management	Yes	Yes	**Identical**
User specific device	Yes	Yes	**Identical**

Item	Proposed Device (This submission)	Primary Predicate Device (K180858)	Equivalency Analysis
profiles and settings			
Store & administer patient data	Yes	Yes	**Identical**
Search & sort patients/documents	Yes	Yes	**Identical**
Surgery recording	Yes	Yes	**Identical**
Image capture	Yes	Yes	**Identical**
Live video	Yes	Yes	**Identical**
Ability to zoom into images	Yes	Yes	**Identical**
Ability to replay surgery video files	Yes	Yes	**Identical**
Export patient and treatment data	Yes	Yes	**Identical**
Import patient and treatment data	Yes	Yes	**Identical**
Cockpits – Display of Devices Data			
Display of data from connected devices e.g., patient name, light intensity, zoom, focus of the surgical microscope, etc.	Yes	Yes	**Identical**
Device Remote Control (Connectivity over the Local Network) (OPMI LUMERA 700, ARTEVO 800, QUATERA 700)			
Receive commands from devices Hand Grips, Foot Control Panel (FCP) buttons or rockers. The function of these inputs can be configured in CALLISTO eye settings e.g., light intensity, focus, zoom, workflow steps forward/backwards	Yes	Yes	**Identical**
Send commands to devices by using the touchscreen of the Panel PC e.g., adjust light intensity, focus, zoom, etc.	Yes	Yes	**Identical**

Item	Proposed Device (This submission)	Primary Predicate Device (K180858)	Equivalency Analysis
QUATERA 700 Remote Control Options Note: The interface that connects CALLISTO eye to surgical microscope OPMI LUMERA 700 is the same that connects CALLISTO eye to QUATERA 700. The remote-control functionality provided by QUATERA 700 is a subset of the functionality of a connected surgical microscope OPMI LUMERA 700 to CALLISTO eye 3.6, the primary predicate device.			
Video recording on/off	Yes	Yes	**Identical**
Assistant function – previous	Yes	Yes	**Identical**
Assistant function-next	Yes	Yes	**Identical**
Display patient data	Yes	Yes	**Identical**
Remote Access (only for certified service engineers) Note: CALLISTO eye Software, version 3.6 as well as version 3.7.2, can be services remotely. A trained representative of Carl Zeiss Meditec (CZM) can access the CALLISTO eye Software over the internet to check the configuration and/or download log files. This remote service is facilitated via the service remote tool, *symmedia SP/I instant VPN*. To establish a remote session, the user needs to acknowledge and confirm the session in the user interface of CALLISTO eye. As transport encryption, *symmedia SP/I instant VPN* uses a Secure Sockets layer protections (SSL) with Public Key RSA 2048-bit and AES 256-bit symmetric encryption.			
Remote service access via internet, User management	Yes	Yes	**Identical**

It is the opinion of Carl Zeiss Meditec AG that the proposed device, CALLISTO eye Software, version 3.7.2, is substantially equivalent to CALLISTO eye Software, version 3.6 for the following reasons:

- The indications for use are identical to the indications for use of the predicate device; and therefore, are deemed to be identical in their relationship to safety and effectiveness.
- The technological characteristics and risk profile of the subject device are equivalent to the predicate device; and therefore, are deemed to be equivalent in their relationship to safety and effectiveness.
- Testing methods are equivalent to those of the predicate; and therefore, are deemed to be equivalent in their relationship to safety and effectiveness.

Therefore, the subject device meets the requirements for substantial equivalence.

7. SUMMARY OF STUDIES

Non-Clinical Performance Testing

Risk Management

Risk management is ensured via a risk analysis, which is used to identify potential hazards and mitigations. These potential hazards are controlled by design means, protection measures and user instructions. To confirm that the measures are effective, and that the product meets its intended uses, verification of requirements and standards was performed as well as validation of the clinical workflow according to ISO 14971. Carl Zeiss Meditec adheres to recognized and established industry practice and relevant international standards where indicated.

Performance Data & Summary of Verification and Validation Activity (21 CFR §807.92(B))

Verification and Validation testing were completed to demonstrate that the device performance complies with specifications and requirements identified for the CALLISTO eye Software. The subject device was tested according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 2005). A portion of software verification may be considered “bench testing.” Each function and/or feature was tested by means of the appropriate test case or test specification. The system verification test report provides the test cases, expected results for each test case and the actual results obtained.

Software verification activities completed were divided into three phases:

- Tests accompanying development (including code inspections)
- Integration test phase – stabilization phase
- System verification

Validation was also conducted for CALLISTO eye according to the Validation Plan to ensure that the device meets the customer’s requirements with respect to performance. The objectives defined in the validation plan were achieved according to the validation results.

Verification and validation activities were successfully completed and prove that CALLISTO eye Software, version 3.7.2, meets the stipulated requirements and performs as intended.

CALLISTO eye Software, version 3.7.2, conforms to the applicable FDA recognized and international IEC and ISO standards with regards to performance and safety:

FDA Recognized Standards	
Identification	**Description**
ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
IEC 62366-1:2015	Medical devices – Application of usability engineering to medical devices
IEC 62304:2015	Medical device software - Software life cycle processes
NEMA PS 3.1-3.20	Digital Imaging and Communications in Medicine (DICOM)

Table: FDA Recognized Standards

Animal/Clinical Performance Testing

Animal and Clinical testing **was not** conducted.

8. CONCLUSION

The modifications to the CALLISTO eye Software, version 3.7.2, consolidate the functions cleared under the previous premarket notifications K180858 (CALLISTO eye 3.6).

The modifications to the subject device do not raise new issues of safety or effectiveness. Therefore, ZEISS believes that the subject device, CALLISTO eye Software, version 3.7.2, is substantially equivalent to the predicate devices, CALLISTO eye (K180858).