December 21, 2023

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

Re: K232944
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: September 15, 2023
Received: September 20, 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bennett N. Walker -S

Digitally signed by Bennett N. Walker -S
Date: 2023.12.21 10:10:54 -05'00'

for 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)*

K232944

Device Name

CALLISTO eye

Indications for Use *(Describe)*

CALLISTO eye Software is a software device intended for remote control of ophthalmic surgical microscopes of ARTEVO 750/850 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:	December 20, 2023
510((k) Number	K232944

2. DEVICE

Device Trade Name:	CALLISTO eye (Software Version 5.0) – K232944
Classification:	21CFR892.2050 Medical image management and processing system
Regulatory Class:	II
Product Code:	NFJ

3. PREDICATE DEVICE

Predicate Device:	CALLISTO eye (Software Version 3.7.2) - K231676 21CFR892.2050
Classification:	Medical image management and processing system
Regulatory Class:	II
Product Code:	NFJ

4. DEVICE DESCRIPTION

CALLISTO eye software version 5.0 is a new release sporting a new user interface but carries the clinical feature set of software version 3.7.2; it supports the digital visualization technology and connectivity of ARTEVO 750 / ARTEVO 850 and provides connectivity to the QUATERA700. CALLISTO eye enables the video visualization of the anterior and posterior segments of the eye and allows the connection and remote control of a surgical microscope with and without OCT Camera. It is designed for high patient throughput and can be used for teaching purposes.

CALLISTO eye is an assistance system that processes real-time video images that can be displayed on the CALLISTO eye Panel PC for viewing by the surgeon and the surgical staff in the operating room. The same video images can be viewed by the surgeon through the eyepiece of the connected surgical microscope. CALLISTO eye provides *Assistant Functions* displaying treatment templates as screen overlays and *Cockpits* displaying patient and device information as screen overlays. Both functions assist the surgeon during procedures such as limbal relaxing incisions, capsulorhexis, and alignment of toric intraocular lenses (TIOL). All treatment templates are based on preoperative clinical data of a particular patient and shall be defined by the surgeon prior surgery. These templates can be displayed on the CALLISTO eye Panel PC, through the eyepiece of the surgical microscope equipped with a data injection system (IDIS (WITH VERSION 5.0 RELABELED AS ADVISION)) of the ARTEVO 750 or on a 3D monitor connected to the ARTEVO 850.

While using “ASSISTANCE markerless” configuration, CALLISTO eye can utilize the preoperative diagnostic data from the Zeiss IOLMaster and may provide the reference and target axis as required to align a toric intraocular lens without the otherwise required ink marks.

Transmission of the diagnostic data from the IOLMaster to CALLISTO eye takes place via USB stick or via a data network connected to a DICOM compatible MIMPS server such as FORUM. The

DICOM functionality allows the indirect communication with other DICOM compatible diagnostic devices and patient information systems to exchange patient data (e.g. medical devices work lists).

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 ARTEVO 750/850 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 5.0) Proposed Device	CALLISTO eye (Version 3.7.2) Predicate (K231676)	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

Feature	CALLISTO eye Software Version 5.0 (Proposed Device)	CALLISTO eye Software Version 3.7.2 (K231676)	Equivalency Analysis
Trade Name	CALLISTO eye	CALLISTO eye	**Identical**
Software version	CALLISTO eye Software version 5.0	CALLISTO eye Software version 3.7.2	**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	Medical image management and processing system	**Identical**
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 ARTEVO 750/850 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** ARTEVO 750/850 are the successor models of OPMI Lumera 700 and ARTEVO 800 respectively which were referred as OPMI Lumera family.
Scope of application	Ophthalmology	Ophthalmology	**Identical**
Patient Contact	No	No	**Identical**
Key components	Software only	Software only	**Identical**
Communication protocols	• TCP/IP • DICOM	• TCP/IP • DICOM • CAN-BUS for EDIS	**Identical** CAN-BUS interface has been removed because all ARTEVO microscopes do not support the EDIS module.

Supported display interface and displays	• HDMI • Panel PC • IDIS (WITH VERSION 5.0 RELABELED AS ADVISION) • ARTEVO 3D Display (in 2D only)	• HDMI • Panel PC • IDIS (WITH VERSION 5.0 RELABELED AS ADVISION) • ARTEVO 3D Display (in 2D only) • EDIS	**Equivalent** All display types are connected via a standard HDMI interface.
Supported video input and formats	• HD-SDI • MPEG 4	• HD-SDI • MPEG 4	**Identical**
Assistance Functions			
Support of Clinical workflows sequence (non-mandatory sequence of the assistant functions)	Live mode => Reference => Incision => Rhexis => Live mode => Z Align => Live mode => LRI	Full screen mode => Reference => Incision => Rhexis => Full screen mode => Z Align => Full screen mode =>	**Equivalent** Live mode in version 5.0 is the same as the full screen mode without overlays in version 3.7.2. However, the full screen mode has to be activated by the surgeon, whereas the Live mode steps can be preconfigured in the workflow by the user.
Representation of the assistance tools guidance templates	2D, line graphics	2D, line graphics	**Identical**
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**
Surgical Microscopes + Keratoscope support (K-Track)	• ARTEVO 750/850 • RESCAN 700 (K180229) • QUATERA 700 (K230858)	• OPMI LUMERA 700 • RESCAN 700 (K180229) • QUATERA 700 (K230858)	**Equivalent**. (Connectivity to OPMI LUMERA 700 / ARTEVO 800 is no longer supported in CALLISTO eye 5.0) Additional support added for RESCAN 700 and QUATERA 700 for the subject device.
Assistance Functions for OCT support			
Remote control of OCT camera RESCAN 700	Yes	Yes	**Identical**
Live view of OCT scans (B-Scans)	Yes	Yes	**Identical**
OCT scan types: 1-Line (1 B-Scan)	Yes	Yes	**Identical**
OCT scan types: 2-Line (2 perpendicular B-Scans of OCT cube)	Yes	Yes	**Identical**
OCT scan types: 5-Line (5 parallel B-Scans)	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 microscope or the 3D monitor as 2D image.	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 • scan length of <9mm scan uses a scan depth of 2.9 mm • scan length of >9mm scan uses a scan depth of 5.8 mm	Yes • scan length of <9mm scan uses a scan depth of 2.9 mm • scan length of >9mm scan uses a scan depth of 5.8 mm	**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	Yes Non-contact type (ZEISS RESIGHT) Contact type	**Identical**
OCT remote control via foot panel	Yes	Yes	**Equivalent** (Identical function but different settings to provide more flexibility to the user)
Access to Microscope live setting with an OCT	Yes	Yes	**Equivalent** (Identical function but with a more streamlined UI for usability)
Non-Medical Device Features (Other Functions)			
User management	Yes	Yes	**Identical**
Patient management	Yes	Yes	**Identical**
User specific device profiles and settings	Yes	Yes	**Identical**
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**
Display of data from connected devices	Yes	Yes	**Equivalent** (Identical data but different presentation on the display)
Receive commands	Yes	Yes	**Equivalent** (Updated interfaces)
Send commands	Yes	Yes	**Equivalent** (Updated interfaces)
Remote service access via internet for service specialists	Not supported	Yes	**N/A** Functionality not provided.
Post surgery document management	Yes	Yes	**Equivalent** (Identical function but with a more streamlined UI)

It is the opinion of Carl Zeiss Meditec AG that the proposed device, CALLISTO eye Software, version 5.0, is substantially equivalent to CALLISTO eye Software, version 3.7.2 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 Device Software Functions (June 2023). 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 5.0, meets the stipulated requirements and performs as intended.

Cybersecurity

CALLISTO eye Software version 5.0 is considered a Cyber device per 524B(c) of the Food, Drug, and Cosmetic Act. ZEISS has followed all recommendations in the FDA guidance document " Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (fda.gov) (September 27, 2023).

ZEISS' methodology to address cybersecurity risks and vulnerabilities was outlined including all assets, threats, vulnerabilities and controls within a Cybersecurity Risk Assessment. ZEISS performed a Cybersecurity Assessment based on VAST Threat Modeling as described in IEC 81001-5-1 under recommendation C10. VAST Threat Modeling was utilized due to its practical nature/approach and is the same threat modeling approach used in the predicate device (K231676).

CALLISTO eye Software, version 5.0, 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 5.0, consolidate the functions cleared under the previous premarket notifications K231676 (CALLISTO eye 3.7.2).

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 5.0, is substantially equivalent to the predicate devices, CALLISTO eye (K231676).