June 20, 2023

Carl Zeiss Meditec Inc
Chaitali Gawde
Senior Regulatory Affairs Specialist
5300 Central Parkway
Dublin, California 94568

Re: K231075
Trade/Device Name: Fluorescence Accessories (YELLOW 560 and INFRARED 800 with FLOW 800 Option)
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic X-Ray System
Regulatory Class: Class II
Product Code: IZI
Dated: April 14, 2023
Received: April 14, 2023

Dear Chaitali Gawde:

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,

Jessica Carr -S

Jessica Carr, PhD
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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)*
K231075

Device Name
Fluorescence Accessories (YELLOW 560 and INFRARED 800 with FLOW 800 Option)

Indications for Use *(Describe)*

• INFRARED 800 with FLOW 800 Option is a surgical microscope accessory intended to be used with a compatible surgical microscope in viewing and visual assessment of intraoperative blood flow in cerebral vascular area including, but not limited to, assessing cerebral aneurysm and vessel branch occlusion, as well as patency of very small perforating vessels. It also aids in the real-time visualization of blood flow and visual assessment of vessel types before and after Arteriovenous Malformation (AVM) surgery. Likewise, INFRARED 800 with FLOW 800 Option used during fluorescence guided surgery aids in the visual assessment of intra-operative blood flow as well as vessel patency in bypass surgical procedures in neurosurgery, plastics and reconstructive procedures and coronary artery bypass graft surgery.

• YELLOW 560 is a surgical microscope accessory intended to be used with a compatible surgical microscope in viewing and visual assessment of intraoperative blood flow in cerebral vascular area including, but not limited to, assessing cerebral aneurysm and vessel branch occlusion, as well as patency of very small perforating vessels. It also aids in the real-time visualization of blood flow and visual assessment of vessel types before and after Arteriovenous Malformation (AVM) surgery.

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 Fluorescence Accessories is provided below.

1. SUBMITTER

Applicant: Carl Zeiss Meditec AG
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Date Prepared: June 12, 2023

2. DEVICE

Device Trade Name:	Fluorescence Accessories (YELLOW 560 and INFRARED 800 with FLOW 800 Option)
Common Name:	Fluorescence accessories for surgical microscope
Classification:	21 CFR 892.1600 Angiographic x-ray system
Regulatory Class:	II
Product Code:	IZI

3. PREDICATE DEVICE

Predicate Device:	YELLOW 560 (K162991), INFRARED 800 with FLOW 800 Option (K100468)
Manufacturer:	Carl Zeiss Meditec AG
Classification:	21 CFR 892.1600 Angiographic x-ray system
Regulatory Class:	II
Product Code:	IZI

4. DEVICE DESCRIPTION

Fluorescence accessories (YELLOW 560 and INFRARED 800 with FLOW 800 option) are an accessory to surgical microscope and are intended for viewing and visual assessment of intra-operative blood flow as well as aids in the real-time visualization of blood flow and visual assessment of vessel types before and after Arteriovenous Malformation (AVM) surgery. The functionality of these filters is derived from their ability to highlight fluorescence emitted from tissue that has been treated with a fluorescence agent by applying appropriate wavelengths of light and utilizing selected filters. This helps a surgeon to visualize different structural body elements (such as vessels, tissue, blood flow, occlusions, aneurysms, etc.) during various intraoperative procedures. The fluorescence accessory can be activated /deactivated by the user via the Graphical User Interface (GUI), foot control panel or the handgrips, for example.

For these accessories to be used with a qualified surgical microscope, the critical components of the surgical microscope need to fulfill the clinically relevant parameters for the Indications for Use of YELLOW 560 and INFRARED 800 with FLOW 800 Option.

The fluorescence accessories are embedded into the surgical microscope. The emission filter wheels are present within the head of the microscope. For filter installation into the surgical microscope, two emissions filters (one for each eyepiece) are placed into each of these filter wheels. Another filter wheel is present in front of the light source, which is installed along with the excitation filter

5. INTENDED USE/INDICATIONS FOR USE

- INFRARED 800 with FLOW 800 Option is a surgical microscope accessory intended to be used with a compatible surgical microscope in viewing and visual assessment of intraoperative blood flow in cerebral vascular area including, but not limited to, assessing cerebral aneurysm and vessel branch occlusion, as well as patency of very small perforating vessels. It also aids in the real-time visualization of blood flow and visual assessment of vessel types before and after Arteriovenous Malformation (AVM) surgery. Likewise, INFRARED 800 with FLOW 800 Option used during fluorescence guided surgery aids in the visual assessment of intra-operative blood flow as well as vessel patency in bypass surgical procedures in neurosurgery, plastics and reconstructive procedures and coronary artery bypass graft surgery.
- YELLOW 560 is a surgical microscope accessory intended to be used with a compatible surgical microscope in viewing and visual assessment of intraoperative blood flow in cerebral vascular area including, but not limited to, assessing cerebral aneurysm and vessel branch occlusion, as well as patency of very small perforating vessels. It also aids in the real-time visualization of blood flow and visual assessment of vessel types before and after Arteriovenous Malformation (AVM) surgery.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

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

Attribute	**Subject Device Fluorescence Accessories**	**Predicate Device YELLOW 560 (K162991)**	**Predicate Device INFRARED 800 with FLOW 800 Option (K100468)**	**Equivalency Analysis**
Manufacturer	Carl Zeiss Meditec AG	Carl Zeiss Meditec AG	Carl Zeiss Meditec AG/ Carl Zeiss Surgical GmbH	Identical (name has been changed)
510(k)	K231075	K162991	K100468	-
Classification Product Code	IZI	IZI	IZI	Identical
Regulation Number	892.1600	892.1600	892.1600	Identical
Classification Advisory Committee	Radiology	Radiology	Radiology	Identical
Review Advisory Committee	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	Identical
Application	Angiography	Angiography	Angiography	Identical

Attribute	Subject Device Fluorescence Accessories	Predicate Device YELLOW 560 (K162991)	Predicate Device INFRARED 800 with FLOW 800 Option (K100468)	Equivalency Analysis
Indications for use	• INFRARED 800 with FLOW 800 Option is a surgical microscope accessory intended to be used with a compatible surgical microscope in viewing and visual assessment of intraoperative blood flow in cerebral vascular area including, but not limited to, assessing cerebral aneurysm and vessel branch occlusion, as well as patency of very small perforating vessels. It also aids in the real-time visualization of blood flow and visual assessment of vessel types before and after Arteriovenous Malformation (AVM) surgery. Likewise, INFRARED 800 with FLOW Option used during fluorescence guided surgery aids in the visual assessment of intra-operative blood flow as well as vessel patency in bypass surgical procedures	N/A	The Carl Zeiss Surgical INFRARED 800 with FLOW Option is a surgical microscope accessory used in viewing and visual assessment of intra-operative blood flow in the cerebral vascular area including, but not limited to, assessing cerebral aneurysm and vessel branch occlusion, as well as patency of very small perforating vessels. It also aids in the real-time visualization of blood flow and visual assessment of vessel types before and after Arteriovenous Malformation (AVM) surgery. Likewise, INFRARED 800 with FLOW Option used during fluorescence guided surgery aids in the visual assessment of intra-operative blood flow as well as vessel patency in bypass surgical procedures in neurosurgery, plastic and reconstructive procedures and coronary artery bypass graft surgery	Equivalent, except for some minor editorial adjustments

Attribute	Subject Device Fluorescence Accessories	Predicate Device YELLOW 560 (K162991)	Predicate Device INFRARED 800 with FLOW 800 Option (K100468)	Equivalency Analysis
	in neurosurgery, plastics and reconstructive procedures and coronary artery bypass graft surgery			
	• YELLOW 560 is a surgical microscope accessory intended to be used with a compatible surgical microscope in viewing and visual assessment of intraoperative blood flow in cerebral vascular area including, but not limited to, assessing cerebral aneurysm and vessel branch occlusion, as well as patency of very small perforating vessels. It also aids in the real-time visualization of blood flow and visual assessment of vessel types before and after Arteriovenous	The ZEISS YELLOW 560 is a surgical microscope accessory used in viewing and visual assessment of intraoperative blood flow in the cerebral vascular area including, but not limited to, assessing cerebral aneurysm and vessel branch occlusion, as well as patency of very small perforating vessels. It also aids in the real-time visualization of blood flow and visual assessment of vessel types before and after Arteriovenous Malformation (AVM) surgery.	N/A	Equivalent, except for some minor editorial adjustments

Attribute	Subject Device Fluorescence Accessories	Predicate Device YELLOW 560 (K162991)	Predicate Device INFRARED 800 with FLOW 800 Option (K100468)	Equivalency Analysis
	Malformation (AVM) surgery.			
Patient Population	Patient population will be all patients undergoing one of the above procedures.	Patient population will be all patients undergoing one of the above procedures.	Patient population will be all patients undergoing one of the above procedures.	Identical
Device Description	Visualization system that utilizes accessory to surgical microscope for intraoperative imaging	Accessory to surgical stereo microscope for intraoperative imaging.	Accessory to surgical stereo microscope for intraoperative imaging.	Equivalent
Accessory to	Unspecified model of surgical microscope	OPMI PENTERO 800/900	OPMI Pentero	Equivalent The subject is not dependent on a specific microscope model and enlists compatible surgical microscope specifications (which fit OPMI PENTERO 800/900 amongst others).
Fluorescent Agent	Sodium Fluorescein FLUORESCITE® may be obtained from Alcon, Inc. AK-FLUOR® may be obtained from Akorn, Inc.	Sodium Fluorescein FLUORESCITE® may be obtained from Alcon, Inc. AK-FLUOR® may be obtained from Akorn, Inc.	N/A	Identical
	Indocyanine Green (ICG) ICG may be obtained from Akorn, Inc., Pulsion Medical	N/A	Indocyanine Green (ICG) ICG may be obtained from Akorn, Inc., Pulsion Medical Systems, or other ICG manufacturers.	Identical

Attribute	Subject Device Fluorescence Accessories	Predicate Device YELLOW 560 (K162991)	Predicate Device INFRARED 800 with FLOW 800 Option (K100468)	Equivalency Analysis
	Systems, or other ICG manufacturers.			
Result	Fluorescent image of the distribution of the dye in the patient's blood vessels during the operation.	Fluorescent image of the distribution of the sodium fluorescein dye in the patient's blood vessels during the operation.	Fluorescent image of the distribution of the dye in the patient's blood vessels during the operation. FLOW 800 provides overview and comparison functions of display and a summary of the dynamic of the fluorescent dye.	Equivalent
Visualization of Real-Time Images	Yes	Yes	Yes	Identical
Sensor	Eyepiece/ video camera (CMOS or CCD sensor) fitting with the related specifications. Minimal pixel resolution: Standard Definition (720 x 480)	Eyepiece/ CMOS video camera High-Definition resolution (1280 x 720)	CCD video camera, near-infrared sensitive Standard Definition resolution (720 x 480)	No specific manufacturer mentioned. Specifications as found under section 10.5.4 must be fulfilled
Visualization Monitor, Interface	microscope Monitor	microscope Monitor	microscope Monitor	Identical
Display	Video and images are presented on monitor. Image may also be displayed in the eyepiece.	Video and images are presented on monitor. Image may also be displayed in the eyepiece.	Video and images are presented on monitor. Image may also be displayed in the eyepiece. Picture in Picture available	Equivalent. 'Picture in Picture available' deleted in the subject device as this is a functionality of the surgical microscope.
Termination of the Fluorescence Accessories	YELLOW 560: N/A INFRARED 800 with FLOW Option:	N/A (A turn off is not necessary because the exposure is in the visible light and covered by the	Determined by surgeon within the first 5 minutes. Automatic termination after 5 minutes	Termination is not relevant for the clinical performance. 5 Minute note is given to the surgeon

Attribute	Subject Device Fluorescence Accessories	Predicate Device YELLOW 560 (K162991)	Predicate Device INFRARED 800 with FLOW 800 Option (K100468)	Equivalency Analysis
	Termination determined by surgeon within the first 5 minutes. After 5 minutes automatic reduction of the excitation light after the typical duration of use (5 minutes) to the value resulting from the limitation depending on the working distance and advice to the user.	general light hazard consideration.)		
Physical Method	White light; Fluorescence	White light; Fluorescence	White light; Fluorescence	Identical
Light Source	Non-laser light source - Minimum Irradiance must be met (see section 10.5.4)	300 Watt Xenon	300 Watt Xenon	Replaced by irradiance required for acceptable illumination
White Light Application Filter	400 nm - 700 nm	400 nm - 700 nm	400 nm - 700 nm	Identical
Fluorescence Excitation	YELLOW 560: 450-510nm Bandpass filter INFRARED 800 with FLOW 800 Option: 400 nm to 780 nm Bandpass filter	450 - 510nm Bandpass filter	400 nm - 780 nm Bandpass filter	Identical
Fluorescence Detection	Filter with high transmission from 530 nm to 700 nm (YELLOW 560) and 815 nm to 925 nm (INFRARED 800 with FLOW 800 Option)	Filter with high transmission from 530 nm to 700 nm	Filter with high transmission from 815 nm to 925 nm	Identical

Attribute	Subject Device Fluorescence Accessories	Predicate Device YELLOW 560 (K162991)	Predicate Device INFRARED 800 with FLOW 800 Option (K100468)	Equivalency Analysis
White light Application	400 – 700 nm	400 – 700 nm	400 – 700 nm	Identical
Distance of imaging head to patient	200 – 625 mm	200 – 500 mm	200 – 500 mm	Equivalent. However, the difference in larger working distances (500 mm and 625 mm) is not relevant as fluorescence is typically used within 200 – 400 mm. The increased range is to accommodate the white light mode.
Camera adaption	Integrated into microscope head	Integrated into microscope head	Integrated into microscope head	Identical
Zoom	Motorized 6:1 or higher	Motorized 6:1	Motorized 6:1	Identical
Autodetection of fluorescence influx	Yes, optional	Yes	Yes	Equivalent, comfort feature of INFRARED 800 with FLOW 800 Option
Autofocus	Yes	Yes	Yes	Identical
Autogain for recording	Yes	Yes	Yes	Identical
Control System	Personal Computer or Embedded Computer	Embedded Computer	Personal Computer	Identical.
Storage	HDD, DVD, SSD or other media	HDD, DVD	HDD, DVD	More storage type media possible.
Available as upgrade for existing microscopes	Yes, via Service Technician	Yes, via Service Technician	Yes, via Service Technician	Identical

7. SUMMARY OF STUDIES

Sterilization and Shelf Life

The device is provided non-sterile. Shelf-Life is not applicable.

Biocompatibility

The device does not have patient-contacting materials; therefore, a biocompatibility assessment is not needed for this device.

Performance Testing - Bench

In order for the Fluorescence Accessories to work, they have to be installed onto a surgical microscope and a software license to the microscope has to be installed. Software verification testing has been performed to demonstrate that software is performing as intended.

Non-clinical system testing provided an evaluation of the performance of the system relevant to each of the system specifications. The functional and system level testing showed that the system met the defined specifications. To ensure that the clinically relevant parameters for the Indications for Use of the fluorescence accessories are fulfilled, the following parameters/specifications were tested:

- Brightness of the fluorescence ocular image
- Excitation wavelength
- Excitation filter
- Emission wavelength
- Emission filter
- Color reproduction of fluorescence ocular images
- Spatial resolution of the ocular image
- Color reproduction of fluorescence video images
- Non-mirrored video image
- Non-rotated video image
- Non-deformed video image
- Centered video image
- Photometric resolution of video image
- Signal-to-noise ratio of the video image (sensitivity)
- Latency of the video image (external monitor)
- Spatial resolution of the video image
- Irradiance (minimum irradiance at maximum illumination)
- Color reproduction of non-fluorescence ocular images
- Color reproduction of non-fluorescence video images

8. CONCLUSION

The indications for use are equivalent to the indications for use of the predicate devices; and therefore, are deemed to be equivalent in their relationship to safety and effectiveness.

The technological characteristics and risk profile of the subject device are equivalent to the predicate devices; and therefore, are deemed to be equivalent in their relationship to safety and effectiveness.

Testing methods are equivalent to those of the predicate devices; and therefore, are deemed to be equivalent in their relationship to safety and effectiveness.

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