July 22, 2022

Carl Zeiss Meditec AG
% Maria Golovina
Head of Regulatory Affairs - USA
5300 Central Parkway
Dublin, California 94568

Re: K211346
Trade/Device Name: BLUE 400
Regulation Number: 21 CFR 882.4950
Regulation Name: Diagnostic Neurosurgical Microscope Filter
Regulatory Class: Class II
Product Code: QFX
Dated: June 16, 2022
Received: June 21, 2022

Dear Maria Golovina:

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,

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211346

Device Name
BLUE 400

Indications for Use *(Describe)*
BLUE 400 is an accessory of the surgical microscope and allows the fluorescence observation of fluorophores with an excitation peak between 400 nm and 410 nm and the fluorescence emission observation comprising the spectrum in a spectral band of 620 - 710 nm.

The ZEISS BLUE 400 is a surgical microscope accessory used in fluorescent visualization of suspected grade III and IV gliomas during neurosurgery.

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 BLUE 400 is provided below.

1. SUBMITTER

Applicant:	Carl Zeiss Meditec AG Goeschwizer Strasse 51-52 D-07745 Jena Germany
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Date Prepared:	July 22, 2022

2. DEVICE

Device Trade Name:	BLUE 400
Classification:	21 CFR 882.4950 Diagnostic Neurosurgical Microscope Filter
Regulatory Class:	II
Product Code:	QFX

3. PREDICATE DEVICE

Predicate Device:	Leica FL400 (DEN180024)
Classification:	21 CFR 882.4950 Diagnostic Neurosurgical Microscope Filter
Regulatory Class:	II
Product Code:	QFX

4. DEVICE DESCRIPTION

The BLUE 400 is an accessory to the Zeiss surgical microscopes (OPMI PENTERO 800, OPMI PENTERO 900, and KINEVO 900), intended to allow intraoperative viewing of malignant glioma tissue under fluorescence. The BLUE 400 accessory is entirely composed of optical filters: the "Excitation" filter and the "Emission" filters. The Excitation filter is designed to filter all light wavelengths except 400 – 470 nanometers and is optimized to pass light between 400 – 410 nanometers. The Emission filters are designed to filter all light wavelengths except 430 – 800 nanometers and is optimized to pass light between 620 – 710 nanometers.

When installed in the surgical microscopes (class I), the BLUE 400 introduces optical filters to the illumination and viewing optical paths. The BLUE 400 includes installation of a software license that facilitates use of the accessory. After the SW license is installed, the user has the option to switch from the normal white light mode of the surgical microscope to the BLUE 400 mode.

The BLUE 400 accessory, when installed in the surgical microscopes, is intended to be used in conjunction with an approved optical imaging agent that is excited mainly in the wavelength range of 400 – 410 nanometers and fluoresces in the wavelength range of 620 – 710 nanometers.

5. INDICATIONS FOR USE

BLUE 400 is an accessory of the surgical microscope and allows the fluorescence observation of fluorophores with an excitation peak between 400 nm and 410 nm and the fluorescence emission observation comprising the spectrum in a spectral band of 620 - 710 nm.

The ZEISS BLUE 400 is a surgical microscope accessory used in fluorescent visualization of suspected grade III and IV gliomas during neurosurgery.

6. SUBSTANTIAL EQUIVALENCE

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

Attribute	**Subject Device** **BLUE 400** **K211346**	**Predicate Device** **Leica FL400** **DEN180024**	**Equivalency Analysis**
Indications for use	BLUE 400 is an accessory of the surgical microscope and allows the fluorescence observation of fluorophores with an excitation peak between 400 nm and 410 nm and the fluorescence emission observation comprising the spectrum in a spectral band of 620 - 710 nm. The ZEISS BLUE 400 is a surgical microscope accessory used in fluorescent visualization of suspected grade III and IV gliomas during neurosurgery.	The Leica FL400 is a surgical microscope accessory filter set for viewing fluorescence of fluorophores comprising an excitation filter for blue spectral range 380 nm – 430 nm and an observation filter comprising the long-wave blue, green, yellow and red spectrum in the spectral band greater than 444 nm. The FL400 is a surgical microscope accessory used in fluorescent visualization of suspected grade III or IV gliomas during neurosurgery.	Similar
Intended Use	Patients undergoing neurological procedures.	Patients undergoing neurological procedures.	Identical
Type of Component	Accessory to the microscope (Filter)	Accessory to the microscope (Filter)	Identical

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

Attribute	Subject Device K211346	Predicate Device DEN180024	Equivalency Analysis
Device name	BLUE 400	Leica FL400	Different
Manufacturer	Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 D-07745 Jena, Germany	Leica Microsystems (Schweiz) AG	Different
Classification Product Code	QFX	QFX	Identical
Regulation #	21 CFR 882.4950 (Diagnostic neurosurgical microscope filter)	21 CFR 882.4950 (Diagnostic neurosurgical microscope filter)	Identical
Fluorescence Excitation Spectral Window	400 nm - 430 nm	380 – 430 nm	Equivalent for fluorescence agent
Spectrum of the Emission Filter	430 - 800 nm	300 – 1100 nm	Equivalent for detecting the fluorescence agent
Combination Device	No	No	Identical
Visualization Result	Fluorescent image of distribution of the accumulated protoporphyrin IX (PpIX) in malignant tissue during operation.	Fluorescent image of distribution of the accumulated protoporphyrin IX (PpIX) in malignant tissue during operation.	Identical
Visualization of Real-Time Images	Yes	Yes	Identical
Visualization on Interface/Display	Yes	Yes	Identical
Light Specifications – Type	White Light – Fluorescence	White Light – Fluorescence	Identical

7. SUMMARY OF STUDIES

Sterilization and Shelf Life

The device is provided non-sterile. Cleaning instructions are provided in the user manual that direct users to follow the cleaning procedures of the surgical operating microscope that the BLUE 400 is installed in. 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 BLUE 400 filter to work, it has to be installed onto a surgical microscope and a software license to the microscope has to be installed. Software verification testing was performed in accordance with FDA Guidance “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” 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.

The testing was completed for the predicate and subject device and the performance of the subject device was compared to the predicate.

Finally, special controls testing has also been performed and met the defined specifications. The following special controls testing has been conducted with and without cover glass.

Test	Test Method Summary	Results
Spectrum of the Illumination Source	The irradiance spectrum (250 nm – 1020 nm, mW/cm^2) of the illumination source was measured and verified with a spectrometer. These measurements were assessed prior to application of the excitation filter module.	Passed
Maximum Power and Irradiance of the Illumination Source	The maximum output power and irradiance of illumination sources were measured and verified with a power meter at the end of the microscope light guide. These measurements were assessed prior to application of the excitation filter module.	Passed
Irradiance Spectrum of the Excitation Light and Spectral Response of the Excitation Filter	The irradiance spectrum (250 nm – 1020 nm) of the illumination light, following passage through the excitation filter module, was measured at a working distance of 30 cm with a spectrometer. The edges at 50% decrease of the blue excitation peak were calculated respectively.	Passed
Maximum Excitation Power and Power Density	The maximum power (mW) and power density (mW/cm^2) of the excitation light was measured with a thermopile, at multiple different working distances (22.5 - 30 cm) and zoom settings, including the maximum and minimum zoom. The power density measurements of the subject device were compared to the predicate device.	Passed
Optical Path Loss	To determine the overall detectable light output and the total losses in relation to device working distance and zoom setting, optical path loss was calculated by dividing the output signal measured at the microscope eyepiece (without emission filter) by the illumination signal measured with a spectrometer at the microscope focal plane for the same zoom setting. A reflection standard (white silicon remission disc) was used at a working distance of 35 cm.	Passed
Spectrum of the Emission Filter	The spectrum (350 nm – 1050 nm) of the emission filter when integrated in the surgical operating	Passed

Test	Test Method Summary	Results
	microscope was measured with a spectroradiometer to include all the coating and optics that affects the spectrum of the observation path. For this test the excitation filter was removed, and a reflection standard was used at the device focal plane with different zoom settings. To compare the light that passes the observation optics and emission filter, the 50% edge of the spectrum was calculated.	
Homogeneity of the Excitation Light at the Focal Point	The reflected signal from a white sheet of paper positioned at 30 cm working distance was imaged by the surgical operating microscope camera and the intensity profile was calculated to demonstrate the homogeneity of the excitation light.	Passed
System Sensitivity	As a diffusely reflecting and fluorescent disc the ZEISS BLUE 400 fluorescent target was used and positioned at a microscope working distance of 22.5 cm. The zoom setting was chosen to lead to the same image size of the target for all three devices. The fluorescence signal in the eyepiece of the subject device was compared to the predicate device.	Passed
Pre-Operative Phantom Test	This test was conducted to demonstrate that the ZEISS BLUE 400 test phantom is suitable for the pre-operative checks of the KINEVO 900 and OPMI PENTERO 900. The phantom has one fluorescent area and was imaged by the surgical microscope camera. The same test was repeated by observation through the microscope eyepiece.	Passed
Spectrum of Camera Filter	The spectrum at the camera interface was measured with a spectroradiometer to demonstrate that camera filter can block near infrared and infrared leakage of excitation light to the camera.	Passed

BLUE 400 has not been evaluated to support the use of the device in a pediatric patient population.

8. CONCLUSION

The indications for use of the subject device, BLUE 400, are equivalent to the indications for use of the predicate device, Leica FL400. The technological characteristics and risk profile of the subject device are similar to the predicate device. Based on the similarities of the indications for use, technological characteristics, and the results of the non-clinical performance testing, the BLUE 400 filter is substantially equivalent to the legally marked predicate device, Leica FL400.