December 29, 2021

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

Re: K211156
Trade/Device Name: CONVIVO In Vivo Pathology Suite
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological Endoscope
Regulatory Class: Class II
Product Code: GWG, OWN, LLZ
Dated: November 23, 2021
Received: November 24, 2021

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,

Xiaolin Zheng, Ph.D.
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)*
K211156

Device Name
CONVIVO In Vivo Pathology Suite

Indications for Use *(Describe)*

The CONVIVO In Vivo Pathology Suite is a system that contains a surgical endo-microscope and a cloud software module. The Suite allows for real-time, remote collaboration between various clinical teams (i.e., neurosurgical and pathology). The device is not intended for diagnostic purposes or to replace standard practices for tumor margin analysis and frozen sections procedures as part of intra-operative consultation.

CONVIVO Surgical Workplace is a surgical endo-microscope that acquires data and creates in-vivo images and image sequences of tissue microstructure. CONVIVO's fiber optic scanner probe is placed in direct contact with tissue during cranial procedures to create in-vivo confocal laser scanning images of the internal microstructure of tissues.

CONVIVO Pathology Workplace (cloud software module) can categorize, archive, and store images created by the acquisition device (such as CONVIVO Surgical Workplace).

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

CONVIVO In Vivo Pathology Suite

In accordance with 21 CFR 807.92, the following summary of information is provided in the 510(k) submission.

Applicant	Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 D-07745 Jena, Germany
Primary Contact	Maria Golovina Head of Regulatory Affairs - USA Carl Zeiss Meditec, Inc. 5300 Central Parkway | Dublin, CA 94568 (925) 216-1078 Phone | (925) 557-4259 Fax E-mail: maria.golovina@zeiss.com (preferred)
Date Prepared	Dec 17, 2021

2. Identification of the Product

Trade Name	CONVIVO In Vivo Pathology Suite
Classification/Common Name	Neurological Endoscope; 21 CFR 882.1480
Device Class	II
Product Code	GWG; OWN; LLZ

3. Predicate Device to which Equivalence is Claimed

Primary Predicate:

Device Name	CONVIVO
Manufacturer	Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 D-07745 Jena, Germany
510(k) Number	K181116
Product Code	GWG; OWN
Classification	Neurological Endoscope

Reference Device:

Device Name	AI Metrics
Manufacturer	AI Metrics LLC 432 Renaissance Dr. Hoover, AL 35226
510(k) Number	K202229
Product Code	LLZ
Classification	Picture Archiving and Communications System per 21CFR892.2050

4. Summary of Device Description

The CONVIVO Surgical Workplace is a Confocal Laser Endomicroscopy (CEM) system intended to create in vivo confocal laser scanning images of the microvasculature and microstructures of the tissue. The system can be applied during surgical procedures and is to be used in direct contact with the tissue. The system is comprised of a confocal processor, handheld scanner probe, computer, touchscreen monitor, cart, and foot control panel.

Sodium fluorescein can be used as contrast agent with CONVIVO without changes to the formulation, mode of action, approved dose, or route of administration; it is systemically administered, and its delivery is independent of CONVIVO. The application of sodium fluorescein in cerebral imaging has been discussed in detail in K181116. The Suite will be used with the fluorescein agent cleared under K181116. The mechanism of action, dosing, and method of application of sodium fluorescein to observing tissue microstructure remains the same as K181116.

Additionally, CONVIVO Surgical Workplace has been configured as a part of a larger CONVIVO In Vivo Pathology Suite which contains the previously cleared system and now includes a cloud-based medical image management and processing system software module (Pathology Workplace) that allows for real-time intraoperative collaboration between surgical teams and pathologists.

5. Indications for Use

The CONVIVO In Vivo Pathology Suite is a system that contains a surgical endo-microscope and a cloud software module. The Suite allows for real-time, remote collaboration between various clinical teams (i.e., neurosurgical and pathology). The device is not intended for diagnostic purposes or to replace standard practices for tumor margin analysis and frozen sections procedures as part of intra-operative consultation.

CONVIVO Surgical Workplace is a surgical endo-microscope that acquires data and creates in-vivo images and image sequences of tissue microstructure. CONVIVO's fiber optic scanner probe is placed in direct contact with tissue during cranial procedures to create in-vivo confocal laser scanning images of the internal microstructure of tissues.

CONVIVO Pathology Workplace (cloud software module) can categorize, archive, and store images created by the acquisition device (such as CONVIVO Surgical Workplace).

6. Substantial Equivalence Comparison to the Predicate Device

Table 1. Subject to Predicate Device Comparison Table

Attribute	Subject Device	Predicate Device (K181116)	Equivalency Analysis
Device name	CONVIVO In Vivo Pathology Suite	CONVIVO	Updated
Manufacturer	Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 D-07745 Jena, Germany	Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 D-07745 Jena, Germany	Identical
510(k)	K211156	K181116	Identical

Attribute	Subject Device	Predicate Device (K181116)	Equivalency Analysis
Classification Product Code	GWG; OWN; LLZ	GWG; OWN	Updated
Regulation #	21 CFR 882.1480 (Neurological Endoscope)	21CFR882.1480 (Neurological Endoscope)	Identical
Classification Adv. Committee	Radiology	Radiology	Identical
Application	Angiography	Angiography	Identical
Review Advisory Committee	Neurology	Neurology	Identical
Combination Device	Yes	Yes	Identical
Indications for use	The CONVIVO In Vivo Pathology Suite is a system that contains a surgical endo-microscope and a cloud software module. The Suite allows for real-time, remote collaboration between various clinical teams (i.e., neurosurgical and pathology). The device is not intended for diagnostic purposes or to replace standard practices for tumor margin analysis and frozen sections procedures as part of intra-operative consultation. CONVIVO Surgical Workplace is a surgical endo-microscope that acquires data and creates in-vivo images and image sequences of tissue microstructure. CONVIVO's fiber optic scanner probe is placed in direct contact with tissue during cranial procedures to create in-vivo confocal laser scanning images of the internal microstructure of tissues. CONVIVO Pathology Workplace (cloud software module) can categorize, archive, and store images created by the acquisition device (such as CONVIVO	The ZEISS CONVIVO is a surgical endomicroscope intended for viewing intra-operative blood flow in the cerebral vascular area, including microvasculature and capillaries. The CONVIVO's fiber optic scanner probe is placed in direct contact with tissue during cranial diagnostic and therapeutic procedures, such as tumor biopsy and resection, to create in-vivo confocal laser scanning images of the internal microstructure of tissues.	Updated

Attribute	Subject Device	Predicate Device (K181116)	Equivalency Analysis
	Surgical Workplace).		

Attribute	Subject Device	Predicate Device (K181116)	Equivalency Analysis
Patient Population	Patients undergoing neurological procedures.	Patients undergoing neurological procedures.	Identical
Device Description	Standalone confocal endomicroscope for intraoperative imaging with high magnification. Live transfer and storage of images to a cloud Medical image management and processing system (Pathology Workplace) via central server.	Standalone confocal endomicroscope for intraoperative imaging with high magnification.	Updated
Basic System Function	View, create and replay fluorescent images of microvasculature/capillaries in the cerebral area.	View, create and replay fluorescent images of microvasculature/capillaries in the cerebral area.	Identical
Imaging System	Confocal laser scanning system	Confocal laser scanning system	Identical
Optical Visualization	Fiber scanner Photo detector	Fiber scanner Photo detector	Identical
Display	Monitor	Monitor	Identical
Fluorescent Agent	Fluorescence imaging system used with: Sodium Fluorescein AK-FLUOR® produced by Akorn, Inc.	Fluorescence imaging system used with: Sodium Fluorescein AK-FLUOR® produced by Akorn, Inc.	Identical
Activation of the fluorescence imaging	The press of a single button of the CONVIVO Surgical Workplace activates imaging.	The press of a single button of the CONVIVO activates imaging.	Identical
Invasivity	Invasive probe used with Sterile Sheath as a sterility barrier.	Invasive probe used with Sterile Sheath as a sterility barrier.	Identical
Result	Fluorescent image with very high magnification of the distribution of the sodium fluorescein dye in the imaged tissue during the operation.	Fluorescent image with very high magnification of the distribution of the sodium fluorescein dye in the imaged tissue during the operation.	Identical

Attribute	Subject Device	Predicate Device (K181116)	Equivalency Analysis
Visualization of Real-Time images	Yes	Yes	Identical
Fluorescence Excitation	488 nm	488 nm	Identical

Attribute	Subject Device	Predicate Device (K181116)	Equivalency Analysis
Observation	Primary filter: Green bandpass filter (515 – 577 nm) Optional filters: Green longpass filter (> 520 nm) Red longpass filter (> 580 nm) Grey filter allows all wavelengths to pass, however, with significantly reduced intensity.	Primary filter: Green bandpass filter (515 – 577 nm) Optional filters: Green longpass filter (> 520 nm) Red longpass filter (> 580 nm) Grey filter allows all wavelengths to pass, however, with significantly reduced intensity.	Identical
Physical Method of Illumination	Laser source (continuous blue light of 488 nm wavelength); Fluorescence	Laser source (continuous blue light of 488 nm wavelength); Fluorescence	Identical
Physical Method of Imaging	Confocal Laser Scanning Microscopy	Confocal Laser Scanning Microscopy	Identical
Distance of Imaging Head to Patient	Direct contact to tissue	Direct contact to tissue	Identical
Auto detection of fluorescence influx	Yes	Yes	Identical
Controlled System	Embedded CPU	Embedded CPU	Identical
Storage	HDD, SSD (ext. thumb drive) Medical image management and processing system (Pathology Workplace)	HDD, SSD (ext. thumb drive)	Updated
Export	Export from Surgical Workplace: Via DICOM PACS, USB thumb drives and live transfer / storage of images to Pathology Workplace. Export / download from Pathology Workplace to local hard drive (DICOM and JPG).	Export from Surgical Workplace: Via DICOM PACS, USB thumb drives.	Updated
Laser	Class 3R laser product	Class 3R laser product	Identical
Cloud Software	Pathology Workplace	No	New

Please note since the FDA Regulation updated certain medical device classification regulations to conform with the Medical Software Provisions in the 21st Century Cures Act (Ref. 86FR20278 Effective April 19, 2021, some of the functionalities below do not fall into the definition of a medical device and are marked with (*). Tables were left ‘as-is’ to facilitate submission review.

Table 2. Subject Device to Reference Device Comparison (Intended Use)

Attribute	Subject Device (K211156)	Reference Device (K202229)	Equivalency Analysis
Medical image viewer*	Browser based web application	Thin client	Equivalent
Software only medical device deployed within a customer's IT infrastructure or on virtualized server technology *	Yes	Yes	Equivalent
Application supports anatomical datasets, such as CT and MR.	Yes, endoscopy	Yes	Equivalent, different image type (MR vs. endoscopy image)
To be used for viewing, manipulation, communication, storage, 3D-visualization and comparison of medical images from multiple imaging modalities and/or multiple time points.	Yes, but for singular modality (neuroendoscopic image generated by CONVIVO acquisition system)	Yes	Equivalent, lesser capability
Provides tools to help the user assess and document the extent of a disease and/or the response to therapy in accordance with user selected standards*	Yes	Yes	Identical
Supports the interpretation and evaluation of examinations and follow up documentation of findings within healthcare institutions, for example, in Radiology, Oncology, and other Medical Imaging environments *	Yes	Yes	Identical
The medical professional retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices. The software is a complement to these standard procedures.	Yes	Yes	Identical
Not be used in mammography.	Yes	Yes	Identical

Table 3. Subject Device to Reference Device Comparison (Technical Characteristics)

Attribute	Subject Device (K211156)	Reference Device (K202229)	Equivalency Analysis
Software-based Picture Archiving and Communication System (PACS) used with general purpose computing hardware. (Please note that "PACS" has not been changed as this was the original table submitted to the FDA by the Reference	Yes	Yes	Identical

Attribute	Subject Device (K211156)	Reference Device (K202229)	Equivalency Analysis
Device before the update in regulation)			
Operating system / Run environment*	Microsoft Azure	Windows 64 / native or virtualized Microsoft Windows platform.	Equivalent
Software delivery method *	Browser based web application	Internet software download	Equivalent
Image navigation tools (pan, zoom, scroll, window/level) *	Yes: Contrast, brightness No: Pan, zoom, scroll, window/level	Yes	Equivalent, lesser functionality
Measurement tools (linear, ROI, HU)	Scale bar only	Yes	Equivalent, lesser functionality
Automatic long and short axis calculations	No	Yes	Not relevant for intended use of subject device
User controls functions with a system of interactive menus and tools *	Yes	Yes	Identical
Semi-automatic lesion segmentation tools	No	Yes	Not relevant for intended use of subject device
Anatomical location labelling tools	Yes	Yes	Equivalent
Display output of measurements and anatomical location information*	Yes	Yes	Equivalent
Tabulation and summation of measurements, lesion categorization and standard evaluation in accordance with selected criteria	No	Yes	Not relevant for intended use of subject device
Longitudinal lesion analysis	No	Yes	Not relevant for intended use of subject device
Image co-registration for viewing images from different time points	No	Yes	Not relevant for intended use of subject device
Report generation*	Yes	Yes	Identical

7. Summary of the Studies

CONVIVO In Vivo Pathology Suite has successfully undergone extensive verification and validation testing to ensure that all requirements for proposed changes have been met.

These included:

- Updated Shelf-Life testing for an extension of shelf-life for a system component
- Updated EMC and Electrical Safety Testing for hardware life-cycle changes
- Updated System and Software Testing for software and interoperability changes

All testing followed internally approved procedures and processes. These procedures and processes are in compliance with referenced standards and FDA guidance documents.

8. Conclusion

The intended use of the subject CONVIVO In Vivo Pathology Suite are the same as the intended use of the predicate device and reference device; and therefore, are deemed to be equivalent in their relationship to safety and effectiveness. An update to interoperability, software modifications, and inclusion of a new accessory (Pathology Workplace) does not change the objective intent of the system.

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

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

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