Carl Zeiss Meditec AG
Ms. Mandy Ambrecht
Senior Staff Regulatory Affairs Specialist
Carl Zeiss Meditec, Inc.
5160 Hacienda Drive
Dublin, California 94568

Re: K181116
  Trade/Device Name: Convivo
  Regulation Number: 21 CFR 882.1480
  Regulation Name: Neurological Endoscope
  Regulatory Class: Class II
  Product Code: GWG, OWN
  Dated: April 25, 2018
  Received: April 27, 2018

Dear Mandy Ambrecht:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Neil R Ogden -S
2018.10.25 16:58:44 -04'00'

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K181116

Device Name
CONVIVO

Indications for Use (Describe)
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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**510(k) SUMMARY**

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92), the 510(k) Summary for the CONVIVO is provided below.

**510(k) Number:** K181116

**Applicant:** Carl Zeiss Meditec AG  
Goeschwitzter Strasse 51-52  
D-07745 Jena, Germany

**Contact:** Mandy Ambrecht  
Senior Staff Regulatory Affairs Specialist  
Carl Zeiss Meditec, Inc.  
5160 Hacienda Drive  
Dublin, CA 94568  
(925) 557-4561 Phone  
mandy.ambrecht@zeiss.com

**Date prepared:** October 25, 2018

**Trade/Proprietary Name:** CONVIVO

**Common Name:** Neurological Endoscope

**Regulation Number:** 21 CFR 882.1480

**Classification Name:** Neurological Endoscope

**Regulatory Class:** II

**Product Code:** GWG  
**Secondary Code:** OWN

**Panel:** Neurology

**Predicate Device:** Cellvizio 100 Series System with Confocal MiniprobeSTM  
(CranioFlexSTM (-,-C) type Confocal MiniprobeSTM) (K180270)

**Reference Device:** YELLOW 560 (K162991)

**Indications for Use**

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.

**Device Description**

The CONVIVO 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.

The Sterile Sheath for CONVIVO is a mandatory single use accessory to the system, intended to provide a sterile barrier between the scanner and the patient’s tissue. Before the scanner is used on the patient, the Sterile Sheath is fitted to the scanner using sterile techniques.

Sodium fluorescein is used as a fluorescence contrast agent to visualize intraoperative cerebral vascular area, including microvasculature/capillaries. 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.

**Testing**

**Sterilization**

The CONVIVO’s Scanner Probe must be used together with the ZEISS Sterile Sheath for CONVIVO, which is a sterile and single use device. The Sterile Sheath for CONVIVO is sterilized with Ethylene Oxide.

The sterilization cycle was validated to achieve a sterility assurance level (SAL) of $10^{-6}$ according to ISO 11135:2014.

In addition, micro-biological barrier function using micro-biological dusting, seal strength, and a dye penetration testing were conducted. The sterility testing after micro-biological dusting was tested according to ASTM F1608.

**Biocompatibility**

The only patient contacting component of the subject device is the Sterile Sheath for CONVIVO. The contact category for this component is Tissue/Bone/Dentin Communicating, < 24 hours.

The materials of the Sterile Sheath were tested in accordance with ISO 10993 including tests for Cytotoxicity, Irritation, Sensitization, Material mediated pyrogenicity, acute systemic toxicity and Chemical information/characterization.
Performance Data
The following performance testing is provided to support the substantial equivalence of the subject device:

- Design Verification Testing – The purpose of the design verification is to demonstrate that the system complies with the established system requirements.
- Laser Safety – The CONVIVO device was assessed for conformity with the relevant requirements of IEC 60825-1.
- Thermal Safety – When operated in intermittent mode, the maximum temperature of the CONVIVO did not exceed the limits established in IEC 60601-1.
- In vivo Testing – The ability to view microstructure of tissues and blood flow intra-operatively was confirmed.

Software Documentation
Software documentation for a MAJOR Level of Concern device is provided in support of the subject device.

Electrical Safety Testing

CONVIVO has demonstrated conformance with the relevant requirements of IEC 60601-2-18:2009 (3rd edition): Particular requirements for the basic safety and essential performance of endoscopic equipment.

Electromagnetic Compatibility Testing
The CONVIVO has demonstrated conformance with the relevant requirements of IEC 60601-1-2 (4th Edition).

Standards
Table 5-1 provides the complete list of standards that are used in the 510(k) to establish device performance and support substantial equivalence.

<table>
<thead>
<tr>
<th>Standards Organization</th>
<th>Standards Number</th>
<th>Standard Title</th>
<th>Standard Version/Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO</td>
<td>14971</td>
<td>Medical Devices – Application of Risk Management to Medical Devices</td>
<td>2007</td>
</tr>
<tr>
<td>Standards Organization</td>
<td>Standards Number</td>
<td>Standard Title</td>
<td>Standard Version/Date</td>
</tr>
<tr>
<td>------------------------</td>
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<td>------------------------------------------------------------</td>
</tr>
<tr>
<td>IEC</td>
<td>60601-1-2</td>
<td>Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests</td>
<td>2014</td>
</tr>
<tr>
<td>IEC</td>
<td>60601-2-18</td>
<td>Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of endoscopic equipment</td>
<td>Ed. 3 / 2009</td>
</tr>
<tr>
<td>IEC</td>
<td>62304</td>
<td>Medical device software – Software life cycle processes</td>
<td>2006</td>
</tr>
<tr>
<td>NEMA</td>
<td>PS 3.1-3.20</td>
<td>Digital Imaging and Communications in Medicine (DICOM)</td>
<td>2016</td>
</tr>
<tr>
<td>AAMI ANSI ISO</td>
<td>10993-1</td>
<td>Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process</td>
<td>2009</td>
</tr>
<tr>
<td>AAMI ANSI ISO</td>
<td>10993-5</td>
<td>Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity</td>
<td>2009</td>
</tr>
<tr>
<td>AAMI ANSI ISO</td>
<td>10993-7</td>
<td>Biological evaluation of medical devices – Part 7: ethylene oxide sterilization residuals. (Sterility)</td>
<td>2008</td>
</tr>
<tr>
<td>AAMI ANSI ISO</td>
<td>10993-10</td>
<td>Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization</td>
<td>2010</td>
</tr>
</tbody>
</table>
**Standards**

<table>
<thead>
<tr>
<th>Standards Organization</th>
<th>Standards Number</th>
<th>Standard Title</th>
<th>Standard Version/Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANSI AAMI ISO</td>
<td>11737-1</td>
<td>Sterilization of health care products - Microbiological methods - Part 1: Determination of the population of microorganisms on product</td>
<td>2006</td>
</tr>
</tbody>
</table>

**Substantial Equivalence Discussion**

The CONVIVO indications for use are equivalent with the Cellvizio 100 Series System with Confocal Miniprobes (CranioFlex™ (-C) type Confocal Miniprobes™) predicate device since both are used to image the same tissue and structure. Also, the general intended use of these devices is the same.

CONVIVO and the predicate device are intended to visualize both microvasculature and internal microstructures. The devices are tools that are used to provide imaging information to the physician.

Both devices are intended to be brought into direct contact with the brain tissue to be examined to create in-vivo confocal laser scanning images of the internal microstructure of tissue.

Furthermore, both devices are confocal laser systems with fiber optic probes and have the identical operation principle. Both devices use a laser source which emits a continuous blue light of 488 nm wavelength. With both devices, a monitor is used to view the images –the images generated with the scanner probe are displayed on the monitor. Both devices can be used in real-time during surgical procedures.
The proposed device, CONVIVO, and the reference device, YELLOW 560 (K162991), have the same intended use. They are both used to examine blood flow in the cerebral vascular area. The ZEISS CONVIVO differs only in the scale of the vasculature that can be imaged, and this difference in technology is supported by performance testing.

While CONVIVO uses a confocal laser scanning system and YELLOW 560 utilizes a surgical stereo microscope, the operation principle is similar. In both cases, Sodium Fluorescein is injected into the patient, excitation light is shined onto the tissue and emitted fluorescent light is used to observe the blood flow and the vasculature within the brain. While the systems have differences, they each have the functions for viewing and recording fluorescent images. Both devices use Sodium Fluorescein as a contrast agent to visualize vascular structures without changes to the formulation, mode of action, approved dose or route of administration. Sodium Fluorescein is used in an identical manner for both devices.

A detailed comparison of the subject device to the predicate device is provided in Table 5-2.

### Table 5-2: Device Comparison Table

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Proposed Device, CONVIVO K181116 (Pending)</th>
<th>Predicate Device, Cellvizio 100 Series System with Confocal Miniprobes™ (CranioFlex™ (-,-C) type Confocal Miniprobes™) K180270</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device name</td>
<td>CONVIVO</td>
<td>Cellvizio 100 Series System with Confocal Miniprobes™ (CranioFlex™ (-,-C) type Confocal Miniprobes™)</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 D-07745 Jena, Germany</td>
<td>Mauna Kea Technologies 9 Rue d'Enghien F-75010 Paris, France</td>
</tr>
<tr>
<td>510(k)</td>
<td>K181116 (Pending)</td>
<td>K180270</td>
</tr>
<tr>
<td>Classification Product Code</td>
<td>GWG (primary product code) OWN (secondary product code)</td>
<td>GWG (primary product code) OWN (secondary product code)</td>
</tr>
<tr>
<td>Regulation No.</td>
<td>21 CFR 882.1480 21 CFR 876.1500</td>
<td>21 CFR 882.1480 21 CFR 876.1500</td>
</tr>
<tr>
<td>Classification</td>
<td>Neurological Devices Panel General &amp; Plastic Surgery</td>
<td>Neurological Devices Panel General &amp; Plastic Surgery and</td>
</tr>
<tr>
<td>Adv. Committee</td>
<td>Neurosurgery</td>
<td>Neurosurgery</td>
</tr>
<tr>
<td>Application</td>
<td>Neurosurgery</td>
<td>Neurosurgery</td>
</tr>
<tr>
<td>Attribute</td>
<td>Proposed Device, CONVIVO K181116 (Pending)</td>
<td>Predicate Device, Cellvizio 100 Series System with Confocal Miniprobes™ (CranioFlex™ (-,-C) type Confocal Miniprobes™) K180270</td>
</tr>
<tr>
<td>----------------</td>
<td>--------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Review Advisory Committee</td>
<td>Neurology</td>
<td>Neurology</td>
</tr>
<tr>
<td>Combination Device</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Indications for use</td>
<td>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.</td>
<td>The Cellvizio® 100 Series systems with Confocal Miniprobes™ are confocal laser systems with fiber optic probes that are intended to allow imaging of the internal microstructure of tissues including, but not limited to, the identification of cells and vessels and their organization or architecture. The CranioFlex™(-,-C) Confocal Miniprobes™ are indicated to provide visualization within central nervous system during cranial diagnostic and therapeutic procedures such as tumor biopsy and resection.</td>
</tr>
<tr>
<td>Device Description</td>
<td>Standalone confocal endomicroscope for intraoperative imaging with high magnification.</td>
<td>Standalone confocal endomicroscope for intraoperative imaging with high magnification.</td>
</tr>
<tr>
<td>Basic System Function</td>
<td>Create in-vivo confocal laser scanning images of the internal microstructure of tissue.</td>
<td>Create in-vivo confocal laser scanning images of the internal microstructure of tissue.</td>
</tr>
<tr>
<td>Imaging System</td>
<td>Confocal laser scanning system with fiber optic probe</td>
<td>Confocal laser scanning system with fiber optic probe</td>
</tr>
<tr>
<td>Optical Visualization</td>
<td>Fiber scanner, Photo detector</td>
<td>Fiber scanner, Photo detector</td>
</tr>
<tr>
<td>Display</td>
<td>Monitor</td>
<td>Monitor</td>
</tr>
<tr>
<td>Attribute</td>
<td>Proposed Device, CONVIVO K181116 (Pending)</td>
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</tr>
<tr>
<td>-------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Fluorescent Agent</td>
<td>Fluorescence imaging system used with Sodium Fluorescein (AK-FLUOR® produced by Akorn, Inc.) yields fluorescent image with very high magnification of the distribution of the sodium fluorescein dye in the imaged tissue during the operation.</td>
<td>Tissue autofluorescence</td>
</tr>
<tr>
<td>Invasivity</td>
<td>Invasive probe used with single use Sterile Sheath as a sterility barrier.</td>
<td>Invasive. The probe needs to be sterilized before use.</td>
</tr>
<tr>
<td>Visualization of Real-Time images</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Fluorescence Excitation</td>
<td>488 nm</td>
<td>488 and 800 nm</td>
</tr>
</tbody>
</table>
| 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. | Information not available.                                                                                                         |
| Physical Method of Illumination | Laser source (continuous blue light of 488 nm wavelength); Fluorescence | Information not available.                                                                                                         |
| Physical Method of Imaging    | Confocal Laser Scanning system                                                                           | Confocal laser scanning system                                                                                                    |
| Export                        | Via DICOM PACS, Shared Drive and USB thumb drives                                                          | Information not available.                                                                                                         |
| Laser                         | Class 3R laser product                                                                                   | Information not available.                                                                                                         |
Conclusion

Both the CONVIVO device and the Cellvizio 100 Series System with Confocal Miniprobes (CranioFlex™ (-,-C) type Confocal Miniprobes™) device have the same intended use for imaging the internal microstructure of tissues. The intended use for the CONVIVO and for the reference device, YELLOW 560, is the same as both devices are used to view intraoperative blood flow and the vasculature in the cerebral area.

In addition, both the CONVIVO device and the Cellvizio 100 Series System with Confocal Miniprobes (CranioFlex™ (-,-C) type Confocal Miniprobes™) device employ confocal laser scanning with fiber optic probes to image internal structures.

Performance data demonstrates the CONVIVO can achieve its intended use. Bench testing (including software and electrical/EMC safety), biocompatibility, sterilization and in vivo testing all support the CONVIVO is as safe and effective as the predicate, and is therefore considered substantially equivalent to the predicate device.

510(k) Summary

Based on the successful verification and validation testing, it is Carl Zeiss Meditec AG’s opinion that the CONVIVO does not introduce any new potential safety risks and is substantially equivalent to, and performs as well as, the predicate device.

Additionally, all testing deemed necessary was conducted on the CONVIVO to ensure that the device is as safe and effective when used in accordance with its Instructions for Use as the predicate device.