September 21, 2023

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

Re: K232159
Trade/Device Name: QEVO System
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological Endoscope
Regulatory Class: Class II
Product Code: GWG
Dated: August 23, 2023
Received: August 24, 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,

Adam D. Pierce -S
Digitally signed by Adam D. Pierce -S
Date: 2023.09.21 08:32:09 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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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)*
K232159

Device Name
QEVO System

Indications for Use *(Describe)*
The QEVO System is intended for viewing internal surgical sites during general surgical procedures and for use in visualization of ventricles and structures within the brain during neurological surgical procedures as well as for viewing internal surgical sites during anterior and posterior spinal procedures, such as nucleotomy, discectomy, and foraminotomy.

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
K232159

In accordance with 21 CFR 807.92 the 510(k) Summary for the QEVO System is provided below.

1. SUBMITTER

Applicant:	Carl Zeiss Meditec AG Goeschwizer Strasse 51-52 D-07745 Jena Germany
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Date Prepared:	September 21, 2023

510(k) Summary
K232159

2. DEVICE

Device Trade Name:	QEVO System
Common Name:	Neurological endoscope
Classification:	21 CFR 882.1480 Neurological endoscope
Regulatory Class:	II
Product Code:	GWG

3. PREDICATE DEVICE (K170667)

Predicate Device:	QEVO System with KINEVO 900
Manufacturer:	Carl Zeiss Meditec AG
Classification:	21 CFR 882.1480 Neurological endoscope
Regulatory Class:	II
Product Code:	GWG

4. DEVICE DESCRIPTION

The QEVO System comprises of the QEVO ECU (Endoscope Control Unit) and QEVO endoscope. The system is intended for viewing internal surgical sites and for use in visualization during general and certain neurosurgical and spinal procedures.

The QEVO System has to be installed and integrated with a host display device (surgical microscope, a monitor, etc). Requirements for physical integration, connectivity, power supply, display resolution, and software integration are established and tested.

5. INTENDED USE/INDICATIONS FOR USE

The QEVO System is intended for viewing internal surgical sites during general surgical procedures and for use in visualization of ventricles and structures within the brain during neurological surgical procedures as well as for viewing internal surgical sites during anterior and posterior spinal procedures, such as nucleotomy, discectomy, and foraminotomy.

510(k) Summary
K232159

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1. Subject to Predicate Device Comparison Table

Device Comparison Table Attribute	**QEVO System (K232159) Subject Device**	**QEVO System with KINEVO 900 (K170667) Predicate Device**	**Equivalency Analysis**
Manufacturer	Carl Zeiss Meditec AG	Carl Zeiss Meditec AG	Identical
510(k) Number	K232159	K170667	N/A
Device Name	QEVO System	QEVO System with KINEVO 900	N/A
Intended Use	The QEVO System is intended for viewing internal surgical sites during general surgical procedures and for use in visualization of ventricles and structures within the brain during neurological surgical procedures as well as for viewing internal surgical sites during anterior and posterior spinal procedures, such as nucleotomy, discectomy, and foraminotomy.	The KINEVO 900 with QEVO System is intended for viewing internal surgical sites during general surgical procedures and for use in visualization of ventricles and structures within the brain during neurological surgical procedures as well as for viewing internal surgical sites during anterior and posterior spinal procedures, such as nucleotomy, discectomy, and foraminotomy.	Equivalent Since, system is disconnected from a specific model of surgical microscope while the QEVO System portion remains identical.
Classification Regulation Product Code	882.1480, Class II Neurological endoscope GWG	882.1480, Class II Neurological endoscope GWG	Identical
System Components	Rigid endoscope, ECU	Rigid endoscope, ECU	Identical
Compatible Host Display Device	Any Zeiss device that is validated to meet the QEVO requirements for physical integration, connectivity, power supply, display resolution, and software integration	KINEVO 900	Equivalent Connectivity parameters identical to those on the KINEVO 900 are available on other Zeiss devices.
Light Transmission	Light source in endoscope main body, light transmission through insertion tube via fiber optics	Light source in endoscope main body, light transmission through insertion tube via fiber optics	Identical

510(k) Summary
K232159

Device Comparison Table Attribute	QEVO System (K232159) Subject Device	QEVO System with KINEVO 900 (K170667) Predicate Device	Equivalency Analysis
Light Source	Integrated LED (intensity adjustable)	Integrated LED (intensity adjustable)	Identical
Image Transmission	Rigid rod lenses + CMOS imaging sensor in endoscope main body	Rigid rod lenses + CMOS imaging sensor in endoscope main body	Identical
Direction of View	45°	45°	Identical
Field of View	100°	100°	Identical
Depth of Field	5-30mm	5-30mm	Identical
Image Resolution	2 Mega Pixel (Full HD imager) 642 TV lines (optical resolution at 15% MTF)	2 Mega Pixel (Full HD imager) 642 TV lines (optical resolution at 15% MTF)	Identical
Image Display	External monitor	External monitor	Identical
2D / 3D Imaging	2D Only	2D Only	Identical
Recording	Via USB-port	Via USB-port	Identical
Insertion Tube Working Length	120mm	120mm	Identical
Insertion Tube Outer Diameter	3.6mm	3.6mm	Identical
Single Use/ Reusable	Reusable	Reusable	Identical
Reprocessing	Manual and automated cleaning, sterilization	Manual and automated cleaning, sterilization	Identical
Electrical Safety	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-18 compliant	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-18 compliant	Identical

7. SUMMARY OF STUDIES

Sterilization and Shelf Life

The QEVO endoscope is used sterile but is not provided sterile. It must be sterilized before first use. It must also be end user cleaned and sterilized between uses. The reprocessing instructions have not been modified and are identical to the predicate device.

Biocompatibility

The only patient contacting component of the subject device is the Insertion tube. The contact category for this component is Tissue/Bone/Dentin Communicating, < 24 hours. The materials were testing in accordance with ISO 10993.

Performance Testing - Bench

There have been no changes in the System Requirements and Verification since the predicate. The following performance testing was provided, to support the substantial equivalence of the subject device:

- Optical Safety - The QEVO Endoscope and ECU were assessed for conformity with the relevant requirements of IEC 62471:2006: Photobiological safety of lamps and lamp systems and were found to comply.

The determination of substantial equivalence was not based on an assessment of performance data.

8. CONCLUSION

The QEVO System and the predicate device are both intended to be used for viewing internal surgical sites during surgical procedures. The indications for use are identical to those of the predicate device with an exception, that the subject device isn't intended to be used with a specific model of surgical microscope.

The technological characteristics and risk profile of the subject device is identical to the predicate device; and therefore, are identical in their relationship to safety and effectiveness.

Testing methods are identical to those of the predicate device; and therefore, are identical in their relationship to safety and effectiveness.

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