510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the QEVO System with KINEVO 900 is provided below.

Device Common Name:	Neurological endoscope
Device Trade Name:	QEVO System with KINEVO 900
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Date Prepared:	August 11, 2017
Classification Regulation:	882.1480, Class II
Classification Name:	Neurological endoscope
Panel:	Neurology
Primary Product Code:	GWG
Predicate Device:	VSII Visionsense Stereoscopic Vision System (K082355)

Indication for Use:

The QEVO System with KINEVO 900 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.

Device Description:

The subject device is a system used for viewing internal surgical sites during surgical procedures. The system consists of the following components:

- QEVO System – QEVO Endoscope Control Unit (ECU) + QEVO endoscope
- KINEVO 900 – surgical microscope

The KINEVO 900 can be operated by the surgeon and surgical assistant as a standard optical surgical microscope, using tubes and eyepieces to view the surgical anatomy. When used with the QEVO System, the KINEVO 900 provides the additional capability to view images from the hand-held QEVO endoscope during neurological and spinal procedures.

The KINEVO 900 is physically connected (via power cable, HDMI/DVI cable, and Ethernet cable) to the QEVO Endoscope Control Unit (ECU). The QEVO endoscope plugs into the QEVO ECU outlet provided on the KINEVO 900.

Non-Clinical Testing

Sterilization:

The steam sterilization process was validated to achieve a sterility assurance level (SAL) of 10^{-6}.

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 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.
- 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.
- Thermal Safety - When operated in intermittent mode, the maximum temperature of the QEVO endoscope did not exceed the limits established in IEC 60601-1.

Software Documentation:

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

Electrical Safety Testing:

The QEVO endoscope, ECU, and cables were assessed for conformity with the relevant requirements of *IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (Edition 3.1, including the US deviations)* and were found to comply.

The QEVO endoscope and ECU were assessed for conformity with the relevant requirements of *IEC 60601-2-18:2009 (3rd edition): Particular requirements for the basic safety and essential performance of endoscopic equipment* and were found to comply.

Electromagnetic Compatibility Testing:

The QEVO endoscope, ECU, and cables were assessed for conformity with the relevant requirements of *IEC 60601-1-2 (4th Edition)* and was found to comply.

Standards:

The table below provides the complete list of standards that are used in the 510(k) to establish device performance and support substantial equivalence:

Standards Organization	Standards Number	Standard Title	Standard Version/Date
AAMI ANSI	60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	2005
IEC	60601-2-18	Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of endoscopic equipment	Ed. 3 / 2009
IEC	60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	Ed. 4 / 2014
IEC	62471	Photobiological safety of lamps and lamp systems	Ed. 1 /2006
AAMI / ANSI / ISO	17665-1	Sterilization of health care products -- moist heat -- part 1: requirements for the development, validation, and routine control of a sterilization process for medical devices	2006 / (R)2013
ANSI/AAMI	ST81	sterilization of medical devices - information to be provided by the manufacturer for the processing of resterilizable medical devices	2004/(R)2010
ANSI/AAMI	ST79	Comprehensive guide to steam sterilization and sterility assurance in health care facilities	2010/A1:2010/A2:2011 /A3:2012/A4:2013/(R)2 014
AAMI ANSI ISO	10993-1	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process	2009
AAMI ANSI ISO	10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	2009
AAMI ANSI ISO	10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	2010
AAMI ANSI ISO	10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	2006

Clinical Testing

Not applicable. Clinical studies are not necessary to establish the substantial equivalence of this device.

Substantial Equivalence Discussion

The predicate device is the previously cleared VSII Visionsense Stereoscopic Vision System (K082355). A detailed comparison of the subject device to the predicate device can be found in the table below.

Device Comparison Table

Attribute	**Subject Device**	**Predicate Device**
Manufacturer	Carl Zeiss Meditec AG	VISIONSENSE, LTD.
510(k) Number	TBD	K082355
Device Name	KINEVO 900 with QEVO System	VisionSense VSII
Classification Regulation **Product Code**	882.1480, Class II Neurological endoscope GWG	888.1100, Class II Arthroscope HRX 882.1480, Class II Neurological endoscope GWG
System Components	Rigid endoscope, ECU	Rigid endoscope, ECU
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
Light Source	Integrated LED (intensity adjustable)	Integrated LED (intensity adjustable)
Image Transmission	Rigid rod lenses + CMOS imaging sensor in endoscope main body	CCD imaging sensor at distal tip
Direction of View	45°	0-70°
Field of View	100°	70°
Depth of Field	5-30mm	7-30mm
Image Resolution	2 Mega Pixel (Full HD imager) 642 TV lines (optical resolution at 15% MTF)	2 Mega Pixel (Full HD imager) N/A (optical resolution)
Image Display	External monitor	External monitor
2D / 3D Imaging	2D Only	2D & 3D
Recording	Via USB-port	Via USB-port

Attribute	Subject Device	Predicate Device
Insertion Tube Working Length	120mm	175mm
Insertion Tube Outer Diameter	3.6mm	4mm
Single Use/ Reusable	Reusable	Reusable
Reprocessing	Manual and automated cleaning, steam sterilization	Manual cleaning, sterilization
Electrical Safety	IEC60601-1, IEC60601-1-2 and IEC60601-2-18 compliant	IEC60601-1, IEC60601-1-2 and IEC60601-2-18 compliant

Substantial Equivalence Conclusion

The subject device and predicate device have the same intended use, for viewing internal surgical sites during general surgical procedures.

The specifications and functionality of the subject device is similar to the predicate devices. Any differences between the devices do not raise new questions of safety and effectiveness. Performance testing demonstrated that the device meets its specifications and intended uses. Therefore, the subject device can be found substantially equivalent to the Visionsense VSII as cleared in K082355.