October 3, 2023

Karl Storz SE & Co. KG
Thomas Ostrowski
Senior Regulatory Affairs Specialist
Dr.-Karl-Storz-StraBe 34
Tuttlingen, Baden-Wurttemberg 78532
Germany

Re: K232406
Trade/Device Name: Karl Storz Or1™ Scb Control (wu300)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: ODA, FET
Dated: August 9, 2023
Received: August 10, 2023

Dear Thomas Ostrowski:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.10.03 09:36:25 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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.

Submission Number *(if known)*

Device Name

KARL STORZ OR1™ SCB CONTROL (WU300)

Indications for Use *(Describe)*

The KARL STORZ OR1™ SCB CONTROL provides central control of compatible medical equipment in the operating room during diagnostic and therapeutic procedures.

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

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Submitter:	KARL STORZ Endoscopy-America, Inc. 2151 E. Grand Avenue EI Segundo, CA 90245
Contact:	Thomas Ostrowski Senior Regulatory Affairs Specialist Phone: +1 (508) 248-2420 E-mail: Thomas.Ostrowski@karlstorz.com
Date of Preparation:	August 9, 2023
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: KARL STORZ OR1™ SCB CONTROL Classification Name: Endoscopic Central Control Unit
Regulatory Class:	II
Product Code:	ODA, FET
Regulation:	876.1500
Predicate Device(s):	Primary Predicate Device: KSEA SCB-RUI K994348 The predicate device has not been subject to a design-related recall.

1. **Device Description**

   The KARL STORZ OR1™ SCB CONTROL is a central control unit which provides a single point of contact in the operating room for centralized control of various medical devices in sterile and non-sterile areas during diagnostic and therapeutic procedures. The system consists of KARL STORZ OR1™ SCB CONTROL software run on a dedicated KARL STORZ OR1™ SCB CONTROL hardware platform (Model Number: WU300) which connects to a touch-sensitive LCD monitor (Model Number: WM100 or WM101).

   The user interface enables central display and control of multiple parameters for KARL STORZ and third-party devices connected via SCB serial cable or ethernet cable to the KARL STORZ OR1™ SCB CONTROL hardware CPU. The equipment controls can be operated via sterile input on the touchscreen monitor with the use of a sterile disposable cover. Outside the sterile area a keyboard or mouse can optionally be used.

The cables used to transfer data and commands between the OR1 SCB CONTROL and the connected medical devices include the following:

- 20040076: RJ-45 Network Cable for Ethernet connection
- 20090370: SCB Cable (2 feet)
- 20090170: SCB Cable (3 feet)
- 20090270: SCB Cable (16 feet)
- 20090470: SCB Cable (25 feet)
- 20090870: SCB Cable (121 feet)

Software Description

The KARL STORZ OR1™ SCB CONTROL software is used to display and enable central control of the parameters of both the SCB equipment connected to the KARL STORZ OR1™ SCB CONTROL and the equipment from other manufacturers intended for this purpose. Information in the form of data and commands are exchanged between the various hardware components of the system via the software main application which processes and distributes data through various sublevel applications to achieve central control and display of controls.

Clinician control of the OR1™ SCB CONTROL occurs via touchscreen monitor where users enter touch commands. These inputs are communicated to the OR1™ SCB CONTROL hardware CPU which determines the appropriate reaction of the system. The CPU formulates the commands and communicates via corresponding protocol to the appropriate device. When the device receives these inputs, it updates its values accordingly and sends back confirmation of the actual values to the CPU which processes and instructs the user interface display to update accordingly.

Environment of Use

The KARL STORZ OR1 SCB CONTROL is intended to be used only in healthcare facilities/hospitals.

2. Indications for Use

The KARL STORZ OR1™ SCB CONTROL provides central control of compatible medical equipment in the operating room during diagnostic and therapeutic procedures.

3. Comparison of Technological Characteristics with the Predicate Device(s)

At a high level, the subject and predicate devices are based on the following same technological elements:

- Windows operating system
- Commercial grade CPU technology
- SCB communication protocol

- Touchscreen user interface

The following technological differences exist between the subject and predicate devices:

- Compatibility with additional medical equipment via serial cable and additional communication protocol
- Operating System update
- Graphical User Interface layout, menu and navigational updates
- CPU hardware specifications (i.e. processor speed, memory)

4. Non-Clinical Performance Data

The following non-clinical performance data were provided in support of the substantial equivalence determination.

Electrical Safety and Electromagnetic Compatibility (EMC)
The system complies with the following standards:

- ANSI/AAMI ES60601-1:2005/(R)2012, and A1:2012, C1:2009(R2012) and A2:2010(R)2012
- IEC 60601-1-2:2014
- IEC 60601-1-6:2010 + AMD1:2013

Software Life Cycle Processes
The system complies with the following standard:

- IEC 62304:2006 + A1:2015

Software Verification and Validation Testing
The system complies with the following guidance:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

5. Clinical Performance Data

Clinical testing was not required to demonstrate the substantial equivalence to the predicate device. Non-clinical verification testing was sufficient to assess safety and effectiveness and to establish the substantial equivalence of the modifications.

6. Conclusion

The conclusions drawn from the non-clinical performance data demonstrated that the subject device is as safe as and as effective as the predicate device. As such, we concluded that the substantial equivalence of the subject and the predicate device has been met, and the differences between the subject and the predicate device do not raise new questions of safety or effectiveness.