



August 15, 2024

Stryker Endoscopy
Sekar Divya
Principal Regulatory Affairs Specialist
5900 Optical Ct
San Jose, California 95138

Re: K241401

Trade/Device Name: Connected OR Hub with Device and Voice Control;
SDC4K Information Management System with Device and Voice Control
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ, HRX
Dated: May 16, 2024
Received: May 17, 2024

Dear Sekar Divya:

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,

Long H. Chen  Digitally signed by Long H. Chen -S
Date: 2024.08.15 14:20:11 -04'00'

Long Chen, 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

Indications for Use

510(k) Number (if known)

K241401

Device Name

Connected OR Hub with Device and Voice Control;
SDC4K Information Management System with Device and Voice Control

Indications for Use (Describe)

Connected OR Hub with Device and Voice Control:

The use of the Connected OR Hub with Device and Voice Control is to allow for voice control and remote control of medical device settings by surgeons or operating room personnel, thereby eliminating the need to manually operate those devices compatible with the Connected OR Hub with Device and Voice Control or to rely on verbal communication between the surgeon and other operating room personnel in order to adjust the surgical equipment. It also has additional digital documentation functionality to electronically capture, transfer, store and display medical device data (non-medical device function), which is independent of the functions or parameters of any attached Stryker device.

SDC4K Information Management System with Device and Voice Control:

The use of the SDC4K Information Management System with Device and Voice Control is to allow for voice control and remote control of medical device settings by surgeons or operating room personnel, thereby eliminating the need to manually operate those devices compatible with the SDC4K Information Management System with Device and Voice Control or to rely on verbal communication between the surgeon and other operating room personnel in order to adjust the surgical equipment. It also has additional digital documentation functionality to electronically capture, transfer, store and display medical device data (non-medical device function), which is independent of the functions or parameters of any attached Stryker device.

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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This 510(k) summary is submitted in accordance with the requirements of 21 C.F.R Part 807.92(c).

510(k) Number: K241401

Submitter:

Applicant:	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138
Contact Person:	Divya Sekar Principal Regulatory Affairs Specialist Email: divya.sekar@stryker.com Phone: 408-754-2473
Date Prepared:	August 14, 2024

Subject Device:

Name of Device:	Connected OR Hub with Device and Voice Control; SDC4K Information Management System with Device and Voice Control
Common or Usual Name	Endoscope and accessories
Classification Name:	Laparoscope, General & Plastic Surgery (21 C.F.R. §876.1500)
Subsequent Classification Name:	Arthroscope, Orthopedic (21 C.F.R. §888.1100)
Regulatory Class:	II
Product Code:	GCJ
Subsequent Product Code	HRX
510(k) Review Panel:	General and Plastic Surgery

Predicate Devices:

Connected OR Hub with Device and Voice Control	K232157 (primary), K230886, K222079
SDC4K Information Management System with Device and Voice Control	

NOTE: The predicate devices have not been subject to a design-related recall.

Device Description:

The Connected OR Hub with Device and Voice Control and SDC4K Information Management System with Device and Voice Control are network compatible hardware platforms that carry out Medical Device Data System (MDDS) functionalities and allows the user to control the state, selection, and settings of compatible connected devices both wired and wirelessly.

The Connected OR Hub with Device and Voice Control and SDC4K Information Management System with Device and Voice Control consists of the following components:

- 1) Base Console which includes:
 - a) Medical Device Data System (MDDS) functionalities
 - b) Optional Device Control feature
 - c) Optional Voice Control feature
 - d) Optional Video Image Processing (VIP) feature
- 2) Device Control Package (software activation USB dongle and a handheld Infrared (IR) remote control)
- 3) Voice Control Package (software activation USB dongle and a wireless headset and base station)
- 4) Video Image Processing package (software activation USB dongle)
- 5) Connected OR Spoke (MDDS)

The Connected OR Hub and SDC4K consoles carry out the Medical Device Data System (MDDS) functionalities (i.e. Non-medical function) and can be marketed as standalone devices. When upgraded with the Device Control and/or Voice Control package, the consoles extend their functionalities to control compatible devices from their touchscreen graphical user interface (GUI), spoken commands via headset (voice control input), and an IR remote control or directional keypad from a camera head (device control input). The received user commands are then processed and communicated with the connected controllable devices, allowing the user to control the state, selection, and settings of those devices. The Connected OR Hub and SDC4K centrally manage foot pedal assignments for the Surgical Drill System and Ultrasonic Aspirator System handpieces, utilizing device or voice control inputs from the systems or directly from the connected foot pedal.

In addition, the Connected OR Hub with Device and Voice Control and SDC4K Information Management System with Device and Voice Control also provide compatibility with the Connected OR Spoke (also referred to as “Spoke”) which is a standalone Class I Medical Device Data System. Once the Connected OR Hub with Device and Voice Control or SDC4K Information Management System with Device and Voice Control is connected to the Spoke, Device Control can be extended to compatible devices which are directly connected to the Spoke. Ethernet-compatible devices are connected to the Secondary Spoke via an ethernet cable/switch.

When upgraded with the Video Image Processing (VIP) package, the Connected OR Hub automates an image enhancing algorithm, and removal of surgical smoke through a compatible insufflator.

Intended Use/Indications for Use:

Subject Devices	Predicate Devices
Connected OR Hub with Device and Voice Control; SDC4K Information Management System with Device and Voice Control	Connected OR Hub with Device and Voice Control; SDC4K Information Management System with Device and Voice Control K232157 (primary), K230886, K222079
<i>NOTE: Connected OR Hub with Device and Voice Control and SDC4K Information Management System with Device and Voice Control have the same Intended Use/Indications for Use; only the names of the device differ.</i> Connected OR Hub with Device and Voice Control: The use of the Connected OR Hub with Device and Voice Control is to allow for remote control and voice control of medical device settings by surgeons or operating room personnel, thereby eliminating the need to manually operate those devices compatible with the Connected OR Hub or to rely on verbal communication between the surgeon and other operating room personnel in order to adjust the surgical equipment. It also has additional digital documentation functionality to electronically capture, transfer, store and display medical device data (non-medical device function), which is independent of the functions or parameters of any attached Stryker device. SDC4K Information Management System with Device and Voice Control: The use of the SDC4K Information Management System with Device and Voice Control is to allow for remote control and voice control of medical device settings by surgeons or operating room personnel, thereby eliminating the need to manually operate those devices compatible with the SDC4K Information Management System with Device and Voice Control or to rely on verbal communication between the surgeon and other operating room personnel in order to adjust the surgical equipment. It also has additional digital documentation functionality to electronically capture, transfer, store and display medical device data (non-medical device function), which is independent of the functions or parameters of any attached Stryker device.	Same as subject device (Connected OR Hub with Device and Voice Control)

Comparison of Technological Characteristics with the Predicate Device:

Item	Subject Devices	Predicate Devices
	Connected OR Hub with Device and Voice Control; SDC4K Information Management System with Device and Voice Control	Connected OR Hub with Device and Voice Control; SDC4K Information Management System with Device and Voice Control
Manufacturer	Stryker	Same as subject devices
Submission Reference	Current Submission	K232157 (primary), K230886, K222079
Principles of Operation	Use of IR remote control for device control and RF communication for voice control of connected devices.	Same as subject devices
Device Components	• Console (Connected OR Hub & SDC4K) • Device Control Package • Voice Control Package • Connected OR Hub VIP Package • Connected OR Spoke	Same as subject devices

Item		Subject Devices	Predicate Devices
		Connected OR Hub with Device and Voice Control; SDC4K Information Management System with Device and Voice Control	Connected OR Hub with Device and Voice Control; SDC4K Information Management System with Device and Voice Control
Feature(s)	Documentation Functionalities (Non-Medical Device functionalities)	Gathering patient demographic data, Capture, Record, Transfer, Display image/video of various formats, Archiving information	Same as subject devices
	Device Control	Remote control of compatible medical device settings	Same as subject devices
	Voice Control	Voice control of compatible medical device settings	Same as subject devices
	Video Image Processing (VIP)	- Smoke Detection - Enhanced Imaging - Smoke Evacuation <i>NOTE: The VIP feature is not available on the SDC4K.</i>	Same as subject devices
Device Control User Interface		- Capacitive Graphical User Interface on LCD touchscreen - Voice recognition and control via wireless headset - Device Control via IR remote control and camera head directional keypad	Same as subject devices
Connection to Controllable Devices		Wired connection: - Using USB port: The controllable devices are connected to the console's USB port(s) via USB cable. - Using SORN port: - The Connected OR Spoke is connected to the console's SORN port via ethernet cable, while the controllable devices are connected to the Connected OR Spoke via USB and/or firewire cables. - The controllable devices are connected to the console's SORN port via ethernet cable/switch. Wireless connection: - The primary Connected OR spoke is connected to the console's SORN port via an ethernet cable, while controllable devices at remote locations within the same OR are connected to the secondary Connected OR Spoke via USB and/or firewire cables. Ethernet-compatible devices are connected to the Secondary Spoke via an ethernet cable/switch. The primary and secondary Spoke act as the wireless transfer medium to transfer device control data to / from the console.	Wired connection: - Using USB port: The controllable devices are connected to the console's USB port(s) via USB cable. - Using SORN port: - The Connected OR Spoke is connected to the console's SORN port via ethernet cable, while the controllable devices are connected to the Connected OR Spoke via USB and/or firewire cables. Wireless connection: - The primary Connected OR spoke is connected to the console's SORN port via an ethernet cable, while controllable devices at remote locations within the same OR are connected to the secondary Connected OR Spoke via device control cables. The primary and secondary Spoke act as the wireless transfer medium to transfer device control data to / from the console.

Item	Subject Devices	Predicate Devices
	Connected OR Hub with Device and Voice Control; SDC4K Information Management System with Device and Voice Control	Connected OR Hub with Device and Voice Control; SDC4K Information Management System with Device and Voice Control
Controllable Devices	Class II Devices: - Surgical Cameras (K132785, K211202, K212511, K214046, K231854, K233327, K240174) - Light Sources (K142310, K151243, K192292, K214046, K221611, K231854) - Insufflators (K063367, K170784, K201361) - Irrigation Pumps (K123441, K191259) - RF Probes and Shaver System (K071859, K160050, K171391) - Wireless Monitor (K081995) - Surgical Drill System (K171840) Unclassified Devices: - Ultrasonic Aspirator System (K213824, K190070) Class I/ II 510(k) exempt devices: - Ceiling Mounted Room Lights (Class II, Product Code: FSY) - Wired Monitor (Class I device)	Class II Devices: - Surgical Cameras (K132785, K211202, K212511, K214046, K231854, K233327, K240174) - Light Sources (K142310, K151243, K192292, K214046, K221611, K231854) - Insufflators (K063367, K170784, K201361) - Irrigation Pumps (K123441, K191259) - RF Probes and Shaver System (K071859, K160050, K171391) - Wireless Monitor (K081995) Class I/ II 510(k) exempt devices: - Ceiling Mounted Room Lights (Class II, Product Code: FSY) - Wired Monitor (Class I device)
Embedded Software Design	Microsoft Windows 10	Same as subject device
Electronic Circuit Design	- Custom designed chipset, storage solution and Capture Card. - CD/DVD drive: Not included in chassis - On-board storage: Hard Disk Drive (HDD) and Solid-State Drive (SSD)	Same as subject device
Video Input and Output	(Connected OR Hub with Device and Voice Control) Input: DVI, RGBHV and HDMI Output: DVI, HDMI (SDC4K Information Management System with Device and Voice Control) Input: HDMI Output: HDMI	Same as subject device
Communication Protocol(s)	Wired: SIDNE, DCM Wireless: DCM, SIDNE, SFB	Same as subject device
Data Transfer, Documentation and Storage (Non-Medical functionality)	- Wireless Standard: WLAN 802.11a/b/g/n/ac - Frequency: 2.4GHz and 5GHz	Same as subject device
Wireless technology for Device and Voice Control	- Voice Control headset (DECT technology) - IR Remote (Infrared) - Connected OR Spoke (WiFi)	Same as subject device
Power rating	100-240VAC ~50/60 Hz, 4A/2A maximum	Same as subject device
Electrical Safety	ANSI/AAMI ES60601-1	Same as subject device
EMC	IEC 60601-1-2	Same as subject device

Summary of technological characteristics:

The subject and the predicate devices (Connected OR Hub with Device and Voice Control and SDC4K information Management System with Device and Voice Control) have the same following technological characteristics (i.e., Principles of operation, Components, User interface, Software design, Circuit design, Video input and output, Communication protocol(s), Wireless technology and Electrical safety / EMC) except for the inter device communication with additional Stryker devices via ethernet-based communication.

Description of nonclinical and clinical tests:

The subject devices (Connected OR Hub with Device and Voice Control and SDC4K information Management System with Device and Voice Control) have been evaluated and conform with recognized standards, device input specifications, user needs and intended uses. A summary of testing is provided in the table below:

Test	Method	Results
Electrical Safety	In accordance with FDA-recognized voluntary consensus standard IEC 60601-1:2020 (19-49)	Pass
EMC	In accordance with FDA-recognized voluntary consensus standard IEC 60601-1-2:2014+A1:2020 (19-36)	Pass
Wireless Technology	- In accordance with FDA-recognized voluntary consensus standard AAMI TIR69:2017/(R2020) (19-22) - In accordance with FDA-recognized voluntary consensus standard ANSI C63.27:2017 (19-29)	Pass
Reprocessing	- In accordance with FDA-recognized voluntary consensus standard ISO 17664-2:2021 (14-579) - In accordance with AAMI TIR12:2020 - In accordance with AAMI TIR 30: 2011	Pass
Software Verification and Validation	In accordance with FDA-recognized voluntary consensus standard IEC 62304:2006+A1:2015 (13-79)	Pass
Cybersecurity	In accordance with FDA Guidance for Industry and Staff – Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (September 2023)	Pass
Usability	In accordance with FDA-recognized voluntary consensus standard IEC 62366-1:2015+AMD1:2020 (5-129)	Pass
Performance – Bench	- In accordance with device input specifications, user needs and intended uses: - Video Compatibility - Environmental Compatibility - Voice Recognition Performance - System Design Validation	Pass

NOTE: The Connected OR Hub with Device and Voice Control and SDC4K Information Management System with Device and Voice Control is not patient contacting; therefore, biocompatibility testing is not required to support the determination of substantial equivalence.

Conclusion:

The modifications to the subject devices do not raise new types of questions regarding safety and effectiveness compared to the predicate devices, and performance testing demonstrates that differences between the subject and predicate devices do not negatively impact the safety and effectiveness of the subject devices compared to the predicates when they are used for the proposed indications for use. The Connected OR Hub with Device and Voice Control and SDC4K Information Management System with Device and Voice Control subject devices in this 510(k) are substantially equivalent to the predicate devices K232157 (primary), K230886, K222079 for the proposed indications for use.