January 13, 2026

Stryker Endoscopy
Rubi Runton
Senior Specialist Regulatory Affairs
5900 Optical Ct.
San Jose, California 95138

RE: K254014
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
Dated: December 15, 2025
Received: December 15, 2025

Dear Rubi Runton:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts, are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.01.13 16:52:24 -05'00'

Colin Kejing 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254014

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.

510(k) Summary – K254014

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92.

Contact Details Submitter:

Applicant Name	Stryker Endoscopy
Applicant Address	5900 Optical Court San Jose, CA 95138
Applicant Contact Telephone	(408) 813-7781
Applicant Contact	Rubi Runton
Applicant Contact Email	rubi.runton@stryker.com
Date Prepared	January 13, 2026

Device Name:

Device Trade Name	Connected OR Hub with Device and Voice Control; SDC4K Information Management System with Device and Voice Control
Common Name	Endoscope and accessories
Classification Name	Laparoscope, General & Plastic Surgery
Regulation Number	21 CFR 876.1500
Product Code	GCJ, HRX

Legally Marketed Predicate Device:

Predicate #	Predicate Trade Name	Product Code
K241401	Connected OR Hub with Device and Voice Control; SDC4K Information Management System with Device and Voice Control	GCJ, HRX

Device Description Summary:

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 consist 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.

In addition, the Connected OR Hub with Device and Voice Control and SDC4K Information Management System with Device and Voice Control provide compatibility with the Connected OR Spoke (also referred to as "Spoke") which is a standalone Medical Device Data System. Once the Connected OR Hub or SDC4K Information Management System Console is connected to the Spoke, Device Control and Voice 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:

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.

Technological Comparison:

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 device
Submission Reference	Current Submission	K241401
Product Code & Regulation	GCJ, HRX 21 CFR 876.1500	Same as subject device
Indications for Use	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	Same as subject device

Item		Subject Devices **Connected OR Hub with Device and Voice Control; SDC4K Information Management System with Device and Voice Control**	Predicate Devices **Connected OR Hub with Device and Voice Control; SDC4K Information Management System with Device and Voice Control**
		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.	
Principles of Operation		Use of IR remote control for device control and RF communication for voice control of connected devices.	Same as subject devices
Intended User		Clinician	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
Consoles' Front Panel Components		LCD touch screen (190 mm x 120 mm) Touch screen controller (smaller touch screen controller board and different chip locations) EMC Shield (different dimensions for compatibility)	LCD touch screen (190 mm x 120 mm) Touch screen controller EMC Shield
Wireless Technology		Wireless Standard: WLAN 802.11a/b/g/n/ac Frequency: 2.4 GHz Operating frequency range: 2412 MHz – 2472 MHz Maximum EIRP Level: 19.96 dBM 5GHz Operating frequency range: 5180 MHz-5240 MHz, 5260 MHz-5320 MHz, & 5470 MHz -5725 MHz Maximum EIRP Level: 22.98 dBm	Wireless Standard: WLAN 802.11a/b/g/n/ac Frequency: 2.4 GHz Operating frequency range: 2400 MHz – 2483.5 MHz Maximum EIRP Level: 15.07 dBM 5GHz Operating frequency range: 5150MHz-5350MHz & 5470MHz -5725MHz Maximum EIRP Level: 14.86 dBm
Feature(s)	**Documentation 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

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**
	Video Image Processing (VIP)	Smoke Detection Enhanced Imaging Smoke Evacuation *NOTE: The VIP feature is not available on the SDC4K.*	Same as subject devices
Device Control User Interface		Capacitive Graphical User Interface on LCD touch screen Voice recognition and control via wireless headset Device Control via IR remote control and camera head directional keypad	Same as subject devices
Controllable Devices		Class II Devices: Surgical Cameras, Light Sources, Insufflators, Irrigation Pumps, RF Probes and Shaver Systems, Wireless Monitors, Surgical Drill Systems Unclassified Devices: Ultrasonic Aspirator System Class I/II 510(K) exempt Devices: Ceiling Mounted Room Lights, Wired Monitors	Same as subject devices

The subject and predicate devices (Connected OR Hub with Device and Voice Control and SDC4K information Management System with Device and Voice Control) share similar technological characteristics in principles of operation, components, user interface, controllable devices, and device components and features. The only technological differences are the subject devices' front panel hardware components and WiFi module in the Connected OR Hub and SDC4K Consoles. The subject devices' front panel hardware was replaced with similar components that provide the same functionality, hence considered similar in technology.

Non-clinical and/or Clinical Tests Summary:

The following non-clinical testing was conducted in accordance with applicable requirements and standards to establish performance and safety of the subject devices (Connected OR Hub with Device and Voice Control and SDC4K Information Management System with Device and Voice Control). All testing concluded with passing results supporting the determination of substantial equivalence:

Software Verification and Validation

Software verification/validation was conducted in accordance with Stryker's Quality Management System and documented to ensure compliance with FDA guidance, "Content of Premarket Submission for Device Software Functions" and IEC 62304:2006+A1:2015 (13-79). The Connected OR Hub and SDC4K software required enhanced documentation. The software verification/validation confirms that the system was appropriately designed, verified and validated.

Performance Testing

Bench performance testing was performed in accordance with device input specifications, user needs and intended uses.

Cybersecurity

Stryker's approach to cybersecurity aligns with FDA Guidance for Industry and Staff – Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (June 2025) and FDA-recognized voluntary consensus standard IEC 81001-1-5 Edition 1.0 2021-12 (13-122). Penetration testing, vulnerability assessments, and threat modeling demonstrate that the subject devices maintain reasonable assurance of cybersecurity and implement appropriate security controls to mitigate cybersecurity risks.

Electrical Safety and EMC

Electrical safety and EMC testing for the subject devices are in accordance with FDA-recognized voluntary consensus standards IEC 60601-1:2020 (19-49), IEC 60601-1-6:2010+A1:2013+A2:2020 (5-132), IEC 60601-1-2:2014+A1:2020 (19-36), and IEC/TR 60601-4-2 Edition 1.0 2016-05 (19-19).

Reprocessing

Reprocessing of the subject devices is in accordance with FDA-recognized voluntary consensus standard ISO 17664-2:2021 (14-579), AAMI TIR12:2020 (14-602), and ANSI/AAMI ST98 (14-583).

The subject devices do not require clinical studies to support the determination of substantial equivalence.

Verification and validation testing demonstrated that the subject devices conform with recognized safety standards, design input specifications, user needs, and intended uses.

Conclusions

The Connected OR Hub with Device and Voice Control and SDC4K Information Management System with Device and Voice Control are substantially equivalent to the predicate devices in design, intended use, principles of operation, technological characteristics, and safety features. The subject devices do not raise different questions of safety and effectiveness when used in accordance with their labeling.