September 9, 2019

Stryker Endoscopy
Meagan Jones
Principal Regulatory Affairs Specialist
5900 Optical Court
San Jose, California 95138

Re: K192172
Trade/Device Name: Connected OR Hub 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: August 9, 2019
Received: August 12, 2019

Dear Meagan Jones:

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192172

Device Name
Connected OR Hub with Device and Voice Control

Indications for Use *(Describe)*

Indications for Use:
The use of the Connected OR Hub with Device and Voice Control system 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.

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

As required by 21 C.F.R Part 807.92(c)

Submitter:

Applicant	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138
FDA Registration number	2936485
Contact Person	Meagan Jones Principal Regulatory Affairs Specialist Phone: (214) 701-2186 Email: meagan.jones@stryker.com
Date Prepared	September 3, 2019

Subject Device:

Name of Device	Connected OR Hub with Device and Voice Control
Common or Usual Name	SDC 4k Information Management System
Classification Name	Laparoscope, General and Plastic Surgery
Regulation number	21 CFR 876.1500
Regulatory Class	Class II
Product Code	GCJ
Subsequent Product Code	HRX

Predicate Device:

Name of Device	Stryker Connected OR Hub with Device and Voice Control, K181258

Note: The predicate device has not been subject to a design-related recall.

Device Description:

The Connected OR Hub with Device and Voice Control is a medical device that allows the surgeon to control the state, selection, and settings of any compatible device attached to it. It also has operating room documentation functionalities (Class I device function) to electronically capture, transfer, store and display medical device data independently of the functions or parameters of the connected medical device.

The Connected OR Hub with Device and Voice Control consists of the following:

a. A Connected OR Hub console (MDDS device)

b. A Device control package (contains an optional software upgrade and a handheld Infrared (IR) remote control) – Class II
c. A Voice control package (contains an optional software upgrade and a headset and base station) – Class II

Intended Use:

The use of the Connected OR Hub with Device and Voice Control system 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.

Indications for Use:

The use of the Connected OR Hub with Device and Voice Control system 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.

Comparison of Technological Characteristics with the Predicate Device:

The proposed device uses the same device control communication protocols as the predicate device, employs the same voice recognition software engine and controls the same types of connected devices as the predicate device. The Connected OR Hub has similar technological characteristics as the predicate device in the following areas:

- Operating principle
- Software architecture
- Electrical characteristics
- Mechanical characteristics
- Communication characteristics
- Performance characteristics
- Compatibility with controllable devices as listed in the product labeling
- Energy source
- Material (no patient contacting material)

In accordance with 21 CFR807.92 (a) (6), a summary of the differences between the proposed and predicate device is provided in the Table below. A complete comparison of the technological characteristics between the proposed and predicate devices is provided in **Section 12- Substantial Equivalence Discussion**.

Feature	**Subject Device - Connected OR Hub with Device and Voice Control**	**Predicate Device - Connected OR Hub with Device and Voice Control, K181258**
Manufacturer	Stryker Endoscopy	Same as subject device
Submission Reference	Current Submission	K181258
Intended use statement	The intended use of the Connected OR Hub with Device and Voice Control system 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 (Class I device function), which is independent of the functions or parameters of any attached device.	Same as subject device

Feature	Subject Device - Connected OR Hub with Device and Voice Control	Predicate Device - Connected OR Hub with Device and Voice Control, K181258
Indications for Use Statement	The intended use of the Connected OR Hub with Device and Voice Control system 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 (Class I device function), which is independent of the functions or parameters of any attached device.	The Connected OR Hub is indicated for use with compatible endoscopic and general surgery devices. The Connected OR Hub can be used in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery wherever a laparoscope, endoscope, or an arthroscope is indicated for use. A few examples of the more common endoscopic surgeries are laparoscopic cholecystectomy, laparoscopic hernia repair, laparoscopic appendectomy, laparoscopic pelvic lymph node dissection, laparoscopically assisted hysterectomy, laparoscopic and thorascopic anterior spinal fusion, anterior cruciate ligament reconstruction, knee arthroscopy, shoulder arthroscopy, small joint arthroscopy, decompression fixation, wedge resection, lung biopsy, pleural biopsy, dorsal sympathectomy, pleurodesis, internal mammary artery dissection for coronary artery bypass, coronary artery bypass grafting where endoscopic visualization is indicated and examination of the evacuated cardiac chamber during performance of valve replacement. Connected OR Hub users are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons, and urologists.
Operating Principles	Use of IR remote control for device control and RF communication for voice control of connected devices.	Same as subject device

Feature	Subject Device - Connected OR Hub with Device and Voice Control	Predicate Device - Connected OR Hub with Device and Voice Control, K181258
Hardware and Software Architecture	No changes to hardware and software architecture for subject device from predicate device.	Same as subject device
Wireless technology (for Class I and non-medical device functionality only)	**Wireless Standard:** WLAN 802.11a/b/g/n/ac **Frequency**: 2.4GHz and 5.2Ghz	Same as subject device
Controllable devices	No changes to list of compatible devices between subject device and predicate device. See Section 12, S*ubstantial Equivalence Discussion* for complete list.	Same as subject device

Performance Testing:

There are no significant design changes to the device leading to or because of the indications for use change. A risk analysis of the indications for use change concluded that the change in indication for use does not raise new issues of safety and effectiveness. Therefore, performance data are not necessary to evaluate the change in indications to a tool type indication.

Conclusions:

The Connected OR Hub with Device and Voice Control is substantially equivalent in design, intended use, principles of operation, technological characteristics and safety features to the predicate device. There are no new issues of safety and/or effectiveness introduced by the subject device when used as instructed.