November 5, 2018

Stryker
Jay Nayar
Staff Regulatory Affairs Specialist
5900 Optical Court
San Jose, California 95138

Re: K181258
Trade/Device Name: ConnectedOR 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: September 26, 2018
Received: September 28, 2018

Dear Jay Nayar:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S

Digitally signed by Long H. Chen -S
Date: 2018.11.05 14:30:52 -05'00'

for

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K181258

Device Name
ConnectedOR Hub with Device and Voice Control

Indications for Use *(Describe)*
The ConnectedOR Hub is indicated for use with compatible endoscopic and general surgery devices. The ConnectedOR 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. ConnectedOR Hub users are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons, and urologists.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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Section 5. 510(k) Summary

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

General Information:

510(k) Sponsor:	Stryker Endoscopy
Address	5900 Optical Court San Jose, CA 95138
FDA Registration Number	2936485
Contact Information	April Malmborg Director, Regulatory Affairs Phone: 408-754-2473 Email: april.malmborg@stryker.com
Date Prepared	11/02/2018

Device Identification:

Proposed Device:

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

Predicate Device:

Trade Name	Stryker SDC3 HD Information Management System with Wireless Device Control Capability
Common Name	SDC3 HD Information Management System
Regulatory Class	II
Classification Name	Laparoscope, General and Plastic Surgery
Regulation Number	21 CFR 876.1500
Product Code	GCJ
Subsequent Product Code	HRX
This device has not been subjected 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 (also referred to as proposed device in the following sections) consists of the following:

a. A Connected OR Hub console
b. A Device control package (contains an optional software upgrade and a handheld Infrared (IR) remote control)
c. A Voice control package (contains an optional software upgrade and a headset and base station)

The proposed device is the latest iteration of the Stryker SDC3 HD Information Management System with wireless device control (hereafter referred to as "predicate device", cleared under **K160332**). The device and voice control features of the proposed device are identical to the predicate device. The operating room documentation functionalities of electronically capturing, transferring, storing and displaying medical device data (Class I device functions) independently of the functions or parameters of any connected medical device remain similar to the predicate device. The proposed device accesses existing controls within each device and **is secondary to the built-in control interface that is already on each device which is identical to the predicate device**

Although the device and voice control characteristics of the proposed device remain the same as compared to the predicate device, the operating system and the hardware were altered significantly leading to the need for a traditional submission per the FDA guidance *Deciding When to Submit a 510(k) for a Change to an Existing Device* and *Deciding When to Submit a 510(k) for a Software Change to an Existing Device*. This submission hence focuses on providing data regarding substantial equivalence of the proposed device (Stryker Connected OR Hub with Device and Voice Control) to the predicate device (Stryker SDC3 HD Information Management System with wireless device and voice control)

Indications for Use:

This submission is not proposing any changes from the indications cleared for the predicate 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.

Intended Use:

This submission is not proposing any changes from the intended uses cleared for the predicate device.

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 the surgeons or operating room personnel, thereby eliminating the need of manual operation of those devices compatible with the Connected OR Hub, or relying upon verbal communications between the surgeon and other personnel in the operating room in order to adjust the surgical equipment. It also has an 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.

Comparison of Technological Characteristics with the Predicate Device:

The Connected OR Hub with Device and Voice Control has the same technological characteristics and design as the predicate with the exception of the software operating system and internal hardware components. The software and hardware were upgraded to support product sustainment, higher processing speeds and higher video resolution. All other technological characteristics of the proposed device are the same as the predicate. 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 principles
- Software architecture
- Electrical characteristics
- Mechanical characteristics
- Communication characteristics
- Performance characteristics
- Compatibility with controllable devices as listed in the product labeling
- Energy source
- Materials (no patient contacting materials)

A complete comparison of technological characteristics between the proposed and predicate devices is provided in **Section 14- Substantial Equivalence Discussion**.

Summary of Non-Clinical Testing Performed:

Test	Method	Results
Device and Voice Control performance	Verified if the performance of device and voice control functionalities with compatible devices is in accordance with device performance specifications.	Pass
Compatibility with Connected OR Spoke	Verified if proposed device was compatible with Connected OR Spoke in accordance with device performance specification.	Pass
Environmental performance	The functionality of the product was verified for the specified operating temperature and humidity range.	Pass
Video Compatibility	Verified if the Connected OR Hub is compatible with supported Cameras, Monitors, and peripherals that the Stryker customers use in the field.	Pass
Memory Profiling and Performance	Verified if the performance and system response times of the Class II Medical Device functionality (Voice and Device Control functionality) while the Connected OR Hub's Class I documentation functionalities is in use are in accordance with device performance specifications.	Pass
Voice Recognition Performance	Verified if the voice recognition performance of the proposed system when voice commands are issued to the system in accordance with device performance specification.	Pass
Voice Accuracy Benchmark	Verified if the voice recognition accuracy of the proposed system when voice commands are issued to the proposed system are equivalent or better to the predicate system.	Pass
Wireless technology performance	Verified the performance and coexistence of the wireless technology in the proposed device in accordance with AAMI TIR 69:2017, ANSI C63.27:2017 and FDA guidance document Radio Frequency Wireless Technology in Medical Devices.	Pass
Electrical Safety	In accordance with ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)	Pass
EMC Testing	In accordance with IEC60601-1-2 Edition 4.0 2014-02	Pass
Usability	Product was designed and tested per IEC 60601-1-6 Edition 3.1 2013-10 and ANSI/AAMI/IEC 62366-1:2015	Pass
System validation and simulated user testing	Validated system performance in accordance with defined user needs and device performance specifications	Pass
Software Validation & Verification	In accordance with IEC 62304 and FDA Guidance Document Principles of Software Validation	Pass

Test	Method	Results
Cybersecurity verification and Network scan	In accordance with device performance specifications, cybersecurity risk assessment and FDA guidance documents - *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*	Pass

***NOTE**: The Connected OR Hub with Device and Voice Control does not require clinical studies to support the determination of substantial equivalence.*

Conclusion:

Based upon the indications for use, intended use, technological characteristic, performance testing and comparison to the predicate device, the Stryker Connected OR Hub with Device and Voice Control raises no new questions of safety and effectiveness as compared to the predicate device.