March 18, 2021

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

Re: K210584
Trade/Device Name: SDC3 HD Information Management System with Wireless Device Control Capability
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: February 25, 2021
Received: February 26, 2021

Dear Divya Sekar:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210584

Device Name
SDC3 HD Information Management System with Wireless Device Control Capability

Indications for Use *(Describe)*
The intended use of the SDC3 HD Information Management System with Wireless Device Control Capability 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 SDC3 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

Submitter:

Applicant	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138
Contact Person	Divya Sekar Staff Regulatory Affairs Specialist Phone: (408) 855-6244 Email: divya.sekar@stryker.com
Date Prepared	February 25, 2021

Subject Device:

The subject device is the SDC3 HD Information Management System with Wireless Device Control Capability:

Name of Device	SDC3 HD Information Management System with Wireless Device Control Capability
Common or Usual Name	SDC3 HD Information Management System
Classification Name	Laparoscope, General and Plastic Surgery
Regulation number	21 C.F.R. §876.1500
Regulatory Class	Class II
Product Code	GCJ; HRX

Predicate Device:

Predicate Device	SDC3 HD Information Management System with Wireless Device Control Capability	K160332

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

Device Description:

The SDC3 HD Information Management System with Wireless Device Control Capability is a network compatible hardware platform that allows the users to control the state, selection, and settings of compatible connected endoscopic and general surgery devices both wired and wirelessly.

The SDC3 HD Information Management System with Wireless Device Control Capability consists of the following:

a. A SDC3 HD Information Management System console (Class I MDDS)
b. A Device Control Package (contains an optional software upgrade and a handheld Infrared (IR) remote control) – Class II

Endoscopy
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c. A Voice Control Package (contains an optional software upgrade and a headset and base station) – Class II
d. Connected OR Spoke (Class I MDDS)

Intended Use / Indications for Use:

Subject Device	Predicate Device
SDC3 HD Information Management System with Wireless Device Control Capability	**SDC3 HD Information Management System with Wireless Device Control Capability**
This Submission	**K160332**
Intended use: The intended use of the SDC3 HD Information Management System with Wireless Device Control Capability 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 SDC3 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.	**Intended use:** Same as subject device
Indications for Use: *Same as the Intended Use:* The intended use of the SDC3 HD Information Management System with Wireless Device Control Capability 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 SDC3 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 SDC3 is indicated for use with compatible endoscopic and general surgery devices. SDC3 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. SDC3 users are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons, and urologists.

Comparison of Technological Characteristics with the Predicate Device:

Feature	Subject Device	Predicate Device
	SDC3 HD Information Management System with Wireless Device Control Capability	**SDC3 HD Information Management System with Wireless Device Control Capability**
	This Submission	**K160332**
Manufacturer	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138	Same as subject device
Principle of Operation	Use of IR remote control for device control and RF communication for voice control of connected devices	Same as subject device
Documentation functionalities (Class I / Non-medical)	• Capture image/ video from live input video; • Support image/video transfer to multiple media; • Display image/ video on LCD touch screen for recording purposes only (not for diagnosis or treatment evaluation)	Same as subject device
Device Control User Interface	• Graphical User Interface on LCD touchscreen • Voice Recognition and Control via wireless headset • Device Control via IR Remote Control Device Control and Camera Head directional keypad	Same as subject device
Connection to Controllable Devices	• Wired connection to the console's device control ports via device control cable. • Wired connection to Connected OR Spoke's device control ports via device control cable. • The console is connected to master Connected OR Spoke via an Ethernet cable, while devices at remote locations within the same OR are connected to the slave Connected OR Spoke via device control cables. The master and slave Spokes act as the wireless transfer medium to transfer device control data to / from the console.	Same as subject device
Controllable devices	Surgical Cameras, Light Sources, Insufflators, Pumps, RF and Shaver System, Wired/Wireless Monitor, Ceiling Mounted Room Lights, Digital Capture Device.	Same as subject device
Operating System Software	Embedded Microsoft Windows 7	Same as subject device
Electronic Circuit Design	Custom Designed Chipset and capture card. CD/DVD drive: Included in Chassis On-board storage: Hard Disk Drive (HDD) only	Same as subject device
Video input and output	Input: S-Video, DVI, RGBHV Output: S-Video, Composite, DVI, RGBHV	Same as subject device
Data Transfer, Documentation and Storage (Class I / Non-Medical)	WLAN 802.11/g/n Frequency Range: 2.4GHz and 5 GHz	Same as subject device

Feature	Subject Device	Predicate Device
	SDC3 HD Information Management System with Wireless Device Control Capability	**SDC3 HD Information Management System with Wireless Device Control Capability**
	This Submission	**K160332**
Wireless Technology for Device and Voice Control	Wireless components used for device and voice control are Voice Control headset (DECT technology), IR Remote (Infrared) and Connected OR Spoke WiFi	Same as subject device
Power Rating	100-240VAC ~50/60 Hz, 4A/2A maximum	Same as subject device
Electrical Safety	IEC 60601-1	Same as subject device
EMC	IEC 60601-1-2	Same as subject device

Performance Testing:

There are no design changes proposed nor necessary to support the change in indications for use. A risk analysis of the indications for use change concluded that the change in indications for use does not raise different questions of safety and effectiveness. Therefore, performance data are not necessary to evaluate the change in indications for use to a tool-type indications for use.

Conclusions:

The SDC3 HD Information Management System with Wireless Device Control Capability is substantially equivalent in design, intended use, principles of operation, technological characteristics and safety features to the predicate device. There are no different questions of safety and effectiveness introduced by the modified SDC3 HD Information Management System with Wireless Device Control Capability when used as instructed.