February 9, 2022

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

Re: K220108
Trade/Device Name: SDC4K Information Management System with Device and Voice Control Package
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ, HRX
Dated: January 11, 2022
Received: January 13, 2022

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)*
K220108

Device Name
SDC4K Information Management System with Device and Voice Control Package

Indications for Use *(Describe)*
The use of the SDC4K Information Management System with Device and Voice Control Package 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 Package 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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This 510(k) summary is submitted in accordance with the requirements of 21 C.F.R Part 807.92(c).

Submitter:

Applicant:	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138
Contact Person:	Divya Sekar Senior Staff Regulatory Affairs Specialist Email: divya.sekar@stryker.com
Date Prepared:	January 11, 2022

Subject Device:

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

Predicate Device:

Connected OR Hub with Device and Voice Control	K212055

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

Device Description:

The SDC4K Information Management System with Device and Voice Control Package is a network compatible hardware platform that carries out Medical Device Data System (MDDS) functionalities and allows the user to control the state, selection, and settings of compatible connected endoscopic and general surgery devices both wired and wirelessly.

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

1) SDC4K Console which includes:
    a) Class I Medical Device Data System (MDDS) functionality
    b) Optional Device Control feature
    c) Optional Voice Control 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) Connected OR Spoke (Class I MDDS)

The SDC4K console carries out the Medical Device Data System (MDDS) functionalities (i.e. Class I device function or Non-medical function) and can be marketed as a standalone device. When upgraded with the Device Control and/or Voice Control package, the SDC4K Console extends its functionality to control compatible devices from its 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 SDC4K Information Management System with Device and Voice Control Package also provides compatibility with the Connected OR Spoke (also referred to as "Spoke") which is a standalone Class I Medical Device Data System. Once the SDC4K is connected to the Spoke, Device Control can be extended to compatible devices connected to the Spoke.

Intended Use/Indications for Use:

Subject Device	Predicate Device
SDC4K Information Management System with Device and Voice Control Package	**Connected OR Hub with Device and Voice Control (K212055)**
The use of the SDC4K Information Management System with Device and Voice Control package 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. *NOTE: Intended use and Indications for Use are the same.*	Same as subject device

Comparison of Technological Characteristics with the Predicate Device:

Item		Subject Device	Predicate Device
		SDC4K Information Management System with Device and Voice Control Package	**Connected OR Hub with Device and Voice Control (K212055)**
Manufacturer		Stryker	Same as subject device.
Principles of Operation		Use of IR remote control for device control and RF communication for voice control of connected devices.	Same as subject device.
Device Components		SDC4K console Device Control Package Voice Control Package Connected OR Spoke	Connected OR Hub console Device Control Package Voice Control Package Connected OR Spoke
Feature(s)	Documentation Functionalities (Class I/Non-Medical Device functionalities)	Gathering patient demographic data, Capture, Record, Transfer, Display image/video of various formats, Archiving information	Same as subject device
	Device Control	Remote control of compatible medical device settings	Same as subject device
	Voice Control	Voice control of compatible medical device settings	Same as subject device
	Video Image Processing (VIP)	N/A – No VIP feature	Smoke Detection Enhanced Imaging Smoke Evacuation
Device Control User Interface		Capacitive Graphical User Interface on LCD touchscreen Voice Recognition and Control via wireless headset Device Control via IR Remote Control Device Control via Camera Head directional keypad	Same as subject device
Connection to Controllable Devices		Wired connection: SDC4K's device control ports via device control cables. Wireless connection: SDC4K is connected to the 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 Spoke act as the wireless transfer medium to transfer device control data to / from SDC4K.	Same as subject device
Controllable Devices		**Stryker Devices: Class II Devices** Surgical Cameras (K132785, K182160, K200310, K202592, K210088, K211202, K212511) Light Sources (K142310, K151243, K173866, K182160, K191046, K192292, K202592, K210088, K211202) Insufflators (K063367, K170784, K201361) Pumps (K123441, K191259) RF and Shaver System (K071859) Wireless Monitor (K081995) **Class I/ II 510(k) exempt devices** Ceiling Mounted Room Lights (Class II) Wired Monitor (Class I device)	Same as subject device.

Item	Subject Device	Predicate Device
	SDC4K Information Management System with Device and Voice Control Package	**Connected OR Hub with Device and Voice Control (K212055)**
Hardware and Software Architecture		
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	Input: HDMI Output: HDMI	Input: DVI, RGBHV and HDMI Output: DVI, HDMI
Wireless Technology		
Data Transfer, Documentation and Storage (Class I/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	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.
Electrical Safety/ EMC		
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.

Performance Data:

Testing was completed in accordance with the following:

Test	Method	Results
Electrical Safety	ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012 IEC 60601-1-6:2010+A1:2013+A2:2020	Pass
EMC	IEC 60601-1-2:2014+A1:2020	Pass
Software Validation & Verification	IEC 62304:2015	Pass
Usability	IEC 62366-1:2020	Pass
Performance – Bench	In accordance with device input specifications, user needs and intended use	Pass

NOTE: The SDC4K Information Management System with Device and Voice Control Package is not patient contacting; therefore, biocompatibility testing is not required to support the determination of substantial equivalence. Additionally, the subject device does not require clinical studies to support the determination of substantial equivalence.

Conclusions:

The SDC4K Information Management System with Device and Voice Control Package 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/or effectiveness introduced by the SDC4K Information Management System with Device and Voice Control Package.