DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 18, 2016

Stryker Endoscopy
Ms. Angela Wong
Staff Regulatory Affairs Analyst
5900 Optical Court
San Jose, California 95138

Re: K160332
Trade/Device Name: Stryker 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, HRX
Dated: April 15, 2016
Received: April 18, 2016

Dear Ms. Wong:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -A

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K160332

Device Name

Stryker SDC3 HD Information Management System with Wireless Device Control Capability

Indications for Use *(Describe)*

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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

5900 Optical Court
San Jose, CA 95138
t: 408 754 2000 f: 408 754 2505
www.stryker.com

stryker®
Endoscopy

510(k) SUMMARY

1) General Information

510(k) Sponsor	Stryker Endoscopy
Address	5900 Optical Court San Jose, CA 95138
FDA Registration Number	2936485
Correspondence Person	Angela Wong Staff Regulatory Affairs Analyst Stryker Endoscopy
Contact Information	Email: angela.wong @ stryker.com Phone: (408) 754-2737
Date Prepared	4 February 2016

2) Device Identification

Proposed Device:

Proprietary Name	Stryker SDC3 HD Information Management System with Wireless Device Control Capability
Common Name	SDC3 HD Information Management System
Classification Name	Laparoscope, General and Plastic Surgery
Regulation Number	21 CFR 876.1500
Product Code	GCJ
Subsequent Product Code	HRX
Regulatory Class	II

Predicate Device:

Proprietary Name	Stryker SDC3 HD Information Management System
Common Name	SDC3 HD Information Management System
Premarket Notification	K121893
Classification Name	Laparoscope, General and Plastic Surgery
Regulation Number	21 CFR 876.1500
Product Code	GCJ
Subsequent Product Code	HRX
Regulatory Class	II

3) Device Description

The Stryker SDC3 HD Information Management System with wireless device control capability (herein referred to as 'proposed device') consists of the following:

1. Stryker SDC3 HD Information Management System (SDC3) that consists of:
    a. A stand-alone console containing SDC3 software version 1.5 and above
    b. A device control package (contains optional software upgrade and a handheld Infrared (IR) remote control)
    c. A voice control package (contains optional software upgrade and a microphone/headset).
2. The Universal Gateway System (Gateway) (acts as a medium for transferring medical device and non-medical device data).

The proposed device is a modification of the *Stryker SDC3 HD Information Management System* (hereafter referred to as "predicate device", cleared under K121893) to add ***wired and wireless device control functionality*** via the Gateway. The wired device control feature (cleared under K121893) and the operating room documentation functionalities of electronically capturing, transferring, storing and displaying of medical device data (Class I device function) provided by the SDC3 remains the same compared to the predicate device. **It should be noted that the device control functionality (both wired and wireless) of the proposed device only provides users with convenient, centralized control of connected (wired and wireless), compatible medical devices. The SDC3 accesses existing controls within each device and is <u>secondary to the built-in control interface that is already on each device.</u>**

The table below summarizes the wireless technology of the proposed device.

Wireless technology and functions	• **Universal Gateway System Wireless Module**: ▪ **Wireless Technology :** 2.4GHz 802.11n (Wi-Fi) wireless radio.
RF Frequencies and Maximum output powers	• **Universal Gateway System Wireless Module**: ○ **RF Frequencies** ▪ 802.11n (ISM band): 2.412 - 2.484 GHz ○ **Maximum Output Power** ▪ 802.11n: 14.5 dBm +/- 1.5 dB ○ **Range at Maximum Output Power** ▪ 100+ feet depending on a number of factors
Wireless Quality of Service	The wireless quality of service needed for wireless device control is the same quality of service that is currently offered by wired device control. Therefore, the Quality of Service

	(QoS) metrics considered for the proposed device accounted for the latency, data rate, accuracy, and communication reliability required to achieve equivalent performance as compared to the wired device control.
Security	It is recommended that the user use WPA2-Enterprise with AES encryption for Wi-Fi security.
Alarm Signals	No alarm signals are transmitted wirelessly in the proposed device. The SDC3 monitors its connection to each Gateway. If a connection to a given Gateway is dropped, an audible alert will be issued by the SDC3 for each compatible device that is connected to that Gateway.
Connection to other wireless devices	No other wireless products or devices are able to establish a wireless device control connection. This is enforced by the proposed device security measures.

4) Indication 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.

5) Intended Use

The intended use of the SDC3 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 SDC3, 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.

6) Comparison of Technological Characteristics with the Predicate Device

The Stryker SDC3 HD Information Management System (SDC3) with wireless device control capability (herein referred to as the proposed device) has the same technological characteristics and design as the predicate device except for the addition of wired and wireless device control functionality via the Gateway. The addition of wired and wireless device control functionality is achieved via a software update to allow the predicate device to be compatible with Universal Gateway System (Gateway), which act as a medium for the SDC3 to transfer device control data wired and wirelessly.

All other technological characteristics of the proposed device are identical to the predicate device. The proposed device uses the same hardware and communication protocols, employs the same voice recognition technology, and is compatible with the same types of controllable devices as listed in the predicate device's product labeling.

In accordance with 21 CFR807.92 (a) (6), a summary of the differences between the proposed and predicate device is provided in Table 5.1. A complete comparison of technological characteristics between the proposed and predicate devices is provided in Section 12 – *Substantial Equivalence Discussion*.

Table 5.1: Differences between the Proposed and Predicate Devices

Feature/ Functions	Proposed Devices	Predicate Devices (K121893)

Wireless Device Control	• **Wireless Technology:**
	  ○ 2.4GHz 802.11n (Wi-Fi) wireless radio.
	• **RF Frequencies:**
	  ○ 802.11 n (ISM band): 2.412 - 2.484 GHz
	• **Maximum Output Power**
	  ○ 802.11 n: 14.5 dBm +/- 1.5 dB
	• **Range at Maximum Output Power**
	  ○ 100+ feet depending on a number of factors
		• Not available

Connection to Compatible Controllable Devices	• Wired connection to SDC3's device control ports via device control cable. • Wired connection to Gateway device control ports via device control cable.	• Wired connection to SDC3's device control ports via device control cable.
Controllable Devices	Same type of currently marketed devices as predicate device. A complete compatible devices list is provided under Section 12 – *Substantial Equivalence Discussion.*	Compatible controllable devices include legacy and currently marketed devices. A complete compatible devices list is provided under Section 12 – *Substantial Equivalence Discussion.*

7) Performance Testing

The Stryker SDC3 HD Information Management System with wireless device control capability was tested for performance in accordance with internal design specifications, applicable performance standards and FDA guidance documents. Risk analysis was carried out in accordance with *ISO 14971:2007 – Medical Devices – Application of Risk Management to Medical Devices*; subsequently design verification/validation activities and corresponding acceptance criteria were identified and performed in accordance to the risk analysis assessment.

Electrical safety and electromagnetic compatibility testing was performed in accordance with the standards listed below. Testing indicates that the proposed device conforms to these standards.

- *ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) - Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*
- *IEC60601-1-2:2007 - Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests*

Software was developed, tested, and verified per *IEC 62304:2006 - Medical Device Software – Software Life Cycle Processes* as well as FDA guidance documents:

- *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*
- *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*
- *Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices*

The software for this device was classified as "moderate" level of concern, since a failure or latent flaw in the software could result in minor injury to the patient or operator.

Performance testing was conducted to ensure that the device functioned as intended and met design specifications, acceptance criteria and the content of the FDA guidance document *"Radio Frequency Wireless Technology in Medical Devices*." Table 5.2 summarized performance verification and validation data provided within this submission.

Table 5.2: Performance Verification and Validation Summary

Test	Test Description
SDC3 and Gateway Software Device Control Verification	Verified device/voice control of compatible devices via Gateway through SDC3's GUI, IR Remote, and supported Camera Head when the devices are connected to Gateway.
SDC3 and Gateway Connectivity Software Verification	Verified the compatibility of SDC3 with Universal Gateway System and the connection security between the SDC3 and the Universal Gateway System.
Software Network Security Verification	Verified network security features of the SDC3.
Wireless Co-existence Verification Test	Verified SDC3's ability to upload case data to an external server wirelessly under co-existence environment.
Benchmarking Test	Verified latency of wireless device control data transmission under co-existence environment, as compared to an identical wired system. Also verified the data accuracy in a non-coexistence environment.
SDC3 and Gateway Accuracy and Reliability Coexistence Report.	Verified accuracy and reliability of wireless device control data transmission under co-existence environment.
Timing Test	Verified that the connection and disconnection times between the SDC3 and the Gateway meet the specification.
Design Validation	Validated expanded functionality of wireless device control to ensure defined user needs and intended use are met under simulated use conditions.

8) Conclusion

Based on the indications for use, intended use, technological characteristics, performance testing and comparison to the predicate device, the Stryker SDC3 HD Information Management System with wireless device control capability raises no new questions of safety and effectiveness as compared to the predicate device.