August 18, 2023

Stryker Corporation
Lauren Bentley
Sr. Manager, Regulatory Affairs
5900 Optical Ct
San Jose, California 95138

Re: K232157
Trade/Device Name: Connected OR Hub with Device and Voice Control, SDC4K Information Management System 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: July 19, 2023
Received: July 20, 2023

Dear Lauren Bentley:

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 and Part 809); 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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.08.18 15:10:05 -04'00'

Mark Trumbore
Assistant Director, THT4A1: Robotically-Assisted Surgical Devices Team
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

IFU

Indications for Use:

Connected OR Hub with Device and Voice Control:

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

SDC4K Information Management System with Device and Voice Control

The use of the SDC4K Information Management System with Device and Voice Control 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.

510(k) Summary

Prepared on: 2023-07-20

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Stryker Corporation
Applicant Address	5900 Optical Ct San Jose CA 95138 United States
Applicant Contact Telephone	(408) 754-2473
Applicant Contact	Ms. Janki Bhatt
Applicant Contact Email	janki.bhatt@stryker.com
Correspondent Name	Stryker Corporation
Correspondent Address	5900 Optical Ct San Jose CA 95138 United States
Correspondent Contact Telephone	(484) 985-0736
Correspondent Contact	Ms. Lauren Bentley
Correspondent Contact Email	lauren.bentley@stryker.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Connected OR Hub with Device and Voice Control; SDC4K Information Management System with Device and Voice Control
Common Name	Endoscope and accessories
Classification Name	Laparoscope, General & Plastic Surgery
Regulation Number	876.1500
Product Code	GCJ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K230886	Connected OR Hub with Device and Voice Control; SDC4K Infor	GCJ

Device Description Summary

21 CFR 807.92(a)(4)

The Connected OR Hub with Device and Voice Control and SDC4K Information Management System with Device and Voice Control are network compatible hardware platforms that carry 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 Connected OR Hub with Device and Voice Control and SDC4K Information Management System with Device and Voice Control consists of the following components:

1) Base Console which includes:
 a) Medical Device Data System (MDDS) functionalities
 b) Optional Device Control feature

c) Optional Voice Control feature
d) Optional Video Image Processing (VIP) 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) Video Image Processing package (software activation USB dongle)
5) Connected OR Spoke (MDDS)

The Connected OR Hub and SDC4K consoles carry out the Medical Device Data System (MDDS) functionalities (i.e. Non-medical function) and can be marketed as standalone devices. When upgraded with the Device Control and/or Voice Control package, the consoles extend their functionalities to control compatible devices from their 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 Connected OR Hub with Device and Voice Control and SDC4K Information Management System with Device and Voice Control provide compatibility with the Connected OR Spoke (also referred to as "Spoke") which is a standalone Medical Device Data System. Once the Connected OR Hub with Device and Voice Control or SDC4K Information Management System with Device and Voice Control is connected to the Spoke, Device Control can be extended to compatible devices which are directly connected to the Spoke.

When upgraded with the Video Image Processing (VIP) package, the Connected OR Hub automates an image enhancing algorithm, and removal of surgical smoke through a compatible insufflator.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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

SDC4K Information Management System with Device and Voice Control
The use of the SDC4K Information Management System with Device and Voice Control 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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject devices, the Connected OR Hub with Device and Voice Control and SDC4K Information Management System with Device and Voice Control have the same indications for use and intended use as the predicate devices.

Technological Comparison

21 CFR 807.92(a)(6)

The subject devices and the predicate devices (Connected OR Hub with Device and Voice Control and SDC4K information Management System with Device and Voice Control) have the same technological characteristics (i.e., principles of operation, components, features, user interface, controllable devices, software design, circuit design, video input and output, communication protocol(s), wireless technology and electrical safety/EMC) with the exception of the Connected OR Hub and SDC4K Consoles' internal hardware components. The subject devices' internal hardware was replaced with similar components that provide the same functionality, hence considered similar in technology.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-clinical testing was designed and developed in accordance with applicable requirements and standards to establish performance and safety of the subject devices (Connected OR Hub with Device and Voice Control and SDC4K information Management System with Device and Voice Control). These include software functional verification testing executed in accordance with IEC 62304:2015, Medical device software – Software life-cycle processes (FDA recognized voluntary consensus standard: 13-79) as well as EMC and Electrical Safety testing in accordance with IEC 60601-1-2:2014+A1:2020, Medical Electrical Equipment – Part 1-2: General requirements for basic

safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and Tests (FDA-recognized voluntary consensus standard: 19-36) and IEC/TR 60601-4-2 Edition 1.0 2016-05, Medical Electrical Equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity; performance of medical electrical equipment and medical electrical systems (FDA-recognized voluntary consensus standard: 19-19), IEC 60601-1 Edition 3.2 2020-08 Consolidated Version, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (FDA recognized voluntary consensus standard: 19-49) and IEC 60601-1-6:2010+A1:2013+A2:2020, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (FDA-recognized voluntary consensus standard: 5-132) . Verification and validation testing successfully completed demonstrated that the device conform with recognized safety standards, design input specifications, user needs and intended uses.

The subject devices do not require clinical studies to support the determination of substantial equivalence.

The Connected OR Hub with Device and Voice Control and SDC4K Information Management System with Device and Voice Control are the same or similar in design, intended use, principles of operation, technological characteristics and safety features to the predicate devices. In summary, the Connected OR Hub with Device and Voice Control and SDC4K Information Management System with Device and Voice Control are the same or similar with respect to safety and effectiveness to the legally marketed predicate devices.