July 28, 2020

Stryker Endoscopy
Meagan Jones
Principal Regulatory Affairs Specialist
5900 Optical Court
San Jose, California 95131

Re: K201434
Trade/Device Name: Connected OR Hub with Device and Voice Control
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: May 28, 2020
Received: June 1, 2020

Dear Meagan Jones:

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 H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2020.07.28 14:57:20 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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and Infection Control Devices
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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)*
K201434

Device Name
Connected OR Hub with Device and Voice Control

Indications for Use *(Describe)*

Intended use/Indications for Use:
The 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 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.

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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This 510(k) summary of safety and effectiveness information is being 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:	Meagan Jones Principal Regulatory Affairs Specialist Phone: (214) 701-2186 Email: meagan.jones@stryker.com
Date Prepared:	May 28, 2020

Subject Device:

Name of Device:	Connected OR Hub with Device and Voice Control
Common or Usual Name	SDC4K Information Management System
Classification Name:	Laparoscope, General & Plastic Surgery
Regulation Number	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(s):

Stryker's Connected OR Hub with Device and Voice Control	K181258, K192172
ZMED VP4000 Video Processor	K130929

NOTE: The predicate devices have not been subject 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 consists of the following:

a. A Connected OR Hub Console

b. A Device control package

c. A Voice control package

The Connected OR Hub with Device and Voice Control with the Video Image Processing (VIP) software feature incorporates and automates an enhanced image algorithm which detects and digitally removes smoke from surgical images; and, automates the detection and initiates smoke evacuation through compatible laparoscopic insufflator(s) during endoscopic procedures.

Indications for Use:

The use of the Connected OR Hub with Voice and Device Control system is to allow for remote and voice 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 Voice and Device 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 (Class I device function), which is independent of the functions or parameters of any attached Stryker device.

Comparison of Technological Characteristics with the Predicate Device:

Item	Subject Device	Predicate Devices	
	Connected OR Hub with Device and Voice Control	**Connected OR Hub with Voice and Device Control (primary predicate)**	**ZMED VP4000 Video Processor (secondary predicate)**
Submission Reference	Current submission	K192172, K181258	K130929
Product Code	GCJ, HRX	Same as subject device	LLZ
Classification	Class II	Class II	Class II
Intended Use /Indications for Use	The 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 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	Same as subject device.	The ZMED VP4000 Video Processor is intended for use in any application where a viewing device (fluoroscope, endoscope, laparoscope, etc.) and monitor are incorporated to aid in diagnosis and treatment of a disease such as an arthroscopy or cholecystectomy.

Item		Subject Device	Predicate Devices	
		Connected OR Hub with Device and Voice Control	**Connected OR Hub with Voice and Device Control (primary predicate)**	**ZMED VP4000 Video Processor (secondary predicate)**
		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.		
Manufacturer		Stryker	Same as subject device	ZMED, Inc.
Principles of Operation		Use of IR remote control for device control and RF communication for voice control of connected devices.	Same as subject device.	Provides enhanced video contrast mapping which facilitates better visualization of subtle (e.g. low contrast) image features
Device Components		• Connected OR Hub console • Device Control Software • Voice Control Software	• Same as subject device	VP4000 Video Processor (with enhanced imaging algorithm)
Feature(s)	Smoke Detection	Manual and automated	N/A – No smoke detection functionality	Not applicable – No smoke detection functionality
	Enhanced Imaging	Manual and automated	Manual (through ZMED VP4000 Video processor)	Automated enhanced imaging
	Smoke Evacuation	Manual and automated	Manual (through Device and Voice control)	Not applicable – No smoke evacuation functionality.
Documentation Functionalities (Class I/Non-Medical Device functionalities)		Capture, transfer and display image/video of various formats for recording purposes only (not for diagnosis or treatment evaluation).	Same as subject device	Not applicable – no Class I/Non-Medical Device functionality included in Clarity.
Device Control User Interface		• Capacitive touch Graphical User Interface on LCD touchscreen • Voice Recognition and Control via wireless headset • Device Control via IR Remote Control	Same as subject device	Operation is required from outside sterile field. Front panel provides On/Off and one-of-six preset selection controls, with additional buttons

Item	Subject Device	Predicate Devices	
	Connected OR Hub with Device and Voice Control	**Connected OR Hub with Voice and Device Control (primary predicate)**	**ZMED VP4000 Video Processor (secondary predicate)**
	• Device Control via Camera Head directional keypad		for custom adjustment of each preset.
Connection to Controllable Devices	Wired connection to Connected OR Hub's device control ports via device control cables. Connected OR Hub 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 Connected OR Hub.	Same as subject device	Not applicable – no devices are controlled with the Clarity Console. It is meant to be connected into a video stream between a camera and surgical display.
Controllable Devices	Surgical Cameras, Light Sources, Insufflators, Pumps, RF and Shaver System, Wireless Monitor	Same as subject device.	Not applicable - No controllable devices.
Embedded Software Design	Embedded Microsoft Windows 10	Same as subject device	Embedded software.
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	Custom design.
Video Input and Output	Input: DVI, RGBHV and HDMI Output: DVI, HDMI	Same as subject device.	Input: DVI, Output: DVI
Power rating	100-240VAC ~50/60 Hz, 4A/2A maximum	Same as subject device.	Same as subject device.
Electrical Safety	IEC 60601-1	Same as subject device.	Same as subject device.

Item	Subject Device	Predicate Devices	
	Connected OR Hub with Device and Voice Control	**Connected OR Hub with Voice and Device Control (primary predicate)**	**ZMED VP4000 Video Processor (secondary predicate)**
EMC	IEC 60601-1-2	Same as subject device.	Same as subject device.

Performance Data:

Testing was completed in accordance with the following:

Test	Method	Conclusion
Software Validation & Verification	IEC 62304:2015	PASS
Usability	IEC 62366-1:2015	PASS
Electrical Safety	ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012	PASS
EMC	IEC 60601-1-2:2014	PASS
Performance - Bench	In accordance with device input specifications and comparative testing to currently legally marketed device.	PASS

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

Conclusions:

The Connected OR Hub with Device and Voice Control is substantially equivalent in design, intended use, principles of operation, technological characteristics and safety features to the predicate devices. There are no new issues of safety and/or effectiveness introduced by the Connected OR Hub with Device and Voice Control.