April 22, 2022

Stryker
Marlene Fraga
Sr. Staff, Regulatory Affairs Specialist, Software Interoperability
5900 Optical Court
San Jose, California 95138

Re: K220895
Trade/Device Name: 1688 4K Camera Control Unit with Advanced Imaging Modality (1688010000), 1688 4K Pendulum Camera Head (1688310130)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ, GWG

Dear Marlene Fraga:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated April 22, 2022. Specifically, FDA is updating this SE Letter to add a secondary product code as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Purva Pandya, OHT4: Office of Surgical and Infection Control Devices, at 240-402-9979, purva.pandya@fda.hhs.gov.

Sincerely,

Purva U. Pandya -S

Purva Pandya, D.Eng.
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

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Sr. Staff, Regulatory Affairs Specialist, Software Interoperability
5900 Optical Court
San Jose, California 95138

Re: K220895
Trade/Device Name: 1688 4K Camera Control Unit with Advanced Imaging Modality (1688010000), 1688 4K Pendulum Camera Head (1688310130)
Regulation Number: 21 CFR 21 C.F.R. §876.1500
Regulation Name: Laparoscope, General And Plastic Surgery
Regulatory Class: Class II
Product Code: GCJ

Dated: March 24, 2022
Received: March 28, 2022

Dear Marlene Fraga:

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,

Purva U. Pandya -S

Purva Pandya, D.Eng.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K220895

Device Name
1688 4K Camera System with Advanced Imaging Modality (AIM)

Indications for Use *(Describe)*
The 1688 Video Camera is indicated for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, neurosurgery and plastic surgery whenever a laparoscope/ endoscope/ arthroscope/ sinuscope is indicated for use. The 1688 Video Camera is indicated for adults and pediatric patients.

A few examples of the more common endoscope surgeries are Laparoscopic cholecystectomy, Laparoscopic hernia repair, Laparoscopic appendectomy, Laparoscopic pelvic lymph node detection, Laparoscopically assisted hysterectomy, Laparoscopic and thorascopic anterior spinal fusion, Anterior cruciate ligament reconstruction, Knee 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.

The users of the 1688 Video Camera are general and pediatric surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons, neurosurgeons 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.

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510(k) Summary K220895

Submitter:

Applicant:	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138
Contact Person:	Marlene Fraga Sr. Staff Regulatory Affairs Specialist, Software Interoperability Email: marlene.fraga@stryker.com
Date Prepared:	March 24, 2022

Subject Device:

Name of Device:	1688 4K Camera System with Advanced Imaging Modality
Common or Usual Name	3-chip Video Camera
Classification Name:	Laparoscope, General and Plastic Surgery (21 C.F.R. §876.1500) Endoscope, Neurological (21 C.F.R. §882.1480)
Regulatory Class:	II
Product Code:	GCJ GWG
510(k) Review Panel:	General & Plastic Surgery Neurology

Predicate Device(s):

1688 4K Camera System with Advanced Imaging Modality	K211202

Device Description:

The 1688 4K Camera System with Advanced Imaging Modality is an endoscopic camera system that produces live video in the surgical field during surgical endoscopic procedures. The system is sensitive in the visible and infrared spectrum. The optical image is transferred from the surgical site to the camera head by a variety of rigid and flexible endoscopes, which are attached to the camera head. The 1688 4K Camera System consists of three main components: (1) a camera control unit (CCU); (2) a camera head with an integral cable that connects to the CCU; and (3) a coupler for attaching an endoscope to the camera head.

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Indications for Use:

Subject Device **1688 4K Camera System** ***This Submission***	Predicate Device **1688 4K Camera System** **(K211202)**
Intended Use: Endoscopic white light and near-infrared illumination and imaging during endoscopic procedures.	**Intended Use:** Same as subject device
Indications for Use: The 1688 Video Camera is indicated for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, neurosurgery and plastic surgery whenever a laparoscope/ endoscope/ arthroscope/ sinuscope is indicated for use. The 1688 Video Camera is indicated for adults and pediatric patients. A few examples of the more common endoscope surgeries are Laparoscopic cholecystectomy, Laparoscopic hernia repair, Laparoscopic appendectomy, Laparoscopic pelvic lymph node detection, Laparoscopically assisted hysterectomy, Laparoscopic and thorascopic anterior spinal fusion, Anterior cruciate ligament reconstruction, Knee 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. The users of the 1688 Video Camera are general and pediatric surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons, neurosurgeons and urologists.	**Indications for Use:** Same as subject device

Comparison of Technological Characteristics with the Predicate Device:

Item	Subject Device **1688 4K Camera System** ***(This Submission)***	Predicate Device **1688 4K Camera System** **(K211202)**
Manufacturer	Stryker	Stryker
Imaging Modes	White Light Near-infrared – fluorescence Near-infrared – transillumination	Same as subject device
Camera System Components	Camera Control Unit Camera Head(s) – Standard, Integrated, Inline, Pendulum, Autoclave[1] Coupler(s) – AIM 4K, AIM 4K Autoclave[1]	Camera Control Unit Camera Head(s) – Standard, Integrated, Inline, Pendulum Coupler(s) – AIM 4K
Principles of Operations	Via an optical endoscope and coupler, light is projected from a light source onto one or more	Same as subject device

Item	Subject Device	Predicate Device
	1688 4K Camera System ***(This Submission)***	**1688 4K Camera System (K211202)**
	complementary metal oxide semiconductor image sensors which acquire a continuous stream of image data. The image data is processed to provide a video stream that is then sent to a display for viewing.	
Safety Standards	IEC 60601-1 IEC 60601-1-6 IEC 60601-2-18 IEC 60601-1-2	Same as subject device
Modes of Operation	Alternate Frame processing Simultaneous Frame processing	Same as subject device
Image Sensor	CMOS image sensor	Same as subject device
Image Processing/ Video Output	Digital	Same as subject device
Resolution	4K (up to 3840 x 2160)	Same as subject device
Frame Rate	60 frames per second	Same as subject device
Camera Control Unit Software	Version: 4.0.19	Version: 4.0.18

[1] *AIM 4K Autoclave Camera Head and Coupler were previously cleared under K212511 on November 4, 2021 as part of the 1688 4K Camera System.*

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Performance Data:

The following performance data were provided in support of the substantial equivalence determination:

Test	Method	Result
Software Verification	IEC 62304:2015	Pass

NOTE: The 1688 4K Camera System is not patient contacting; therefore, biocompatibility testing was not required to support the determination of substantial equivalence. Additionally, the device modifications to the 1688 4K Camera System do not require clinical studies to support the determination of substantial equivalence.

Conclusions:

The 1688 4K Camera System is substantially equivalent in design, intended use, principles of operation, technological characteristics and safety features to the predicate devices. There are no different issues of safety and/or effectiveness introduced by the 1688 4K Camera System.