Stryker
April Malmborg
Director, Regulatory Affairs
5900 Optical Ct
San Jose, California 95138

Re: K200310
Trade/Device Name: 1688 Pendulum 4K Camera Head with Integrated Coupler, 1688 4K Camera Control Unit with Advanced Imaging Modality
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: February 4, 2020
Received: February 6, 2020

Dear April Malmborg:

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,

Jessica Mavadia-Shukla
Acting 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)*

K200310

Device Name
1688 4K Camera System with Advance Imaging Modality

Indications for Use *(Describe)*

The 1688 Video Camera is indicated for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery whenever a laparoscope/ endoscope/ arthroscope is indicated for use. 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 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.

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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:	April Malmborg, RAC Director, Regulatory Affairs Phone: (408) 754-2473 Facsimile: (408) 754-2598 Email: april.malmborg@stryker.com
Date Prepared:	February 4, 2020

Subject Device:

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

Predicate Device(s):

1688 4K Camera System with Advance Imaging Modality	K182160

NOTE: The predicate devices have not been subject to a design-related recall.

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 scopes, 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 (integrated or standard); and (3) a coupler for attaching an endoscope to the camera head.

Indications for Use:

The 1688 Video Camera is indicated for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery whenever a laparoscope/ endoscope/ arthroscope is indicated for use. 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 surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.

Comparison of Technological Characteristics with the Predicate Device:

Item	Subject Device	Predicate Device
	1688 4K Camera System	1688 4K Camera System
Manufacturer	Stryker	Same as subject device
Submission Reference	Current Submission	K182160
Intended Use	Endoscopic visible and near-infrared light illumination and imaging during surgical endoscopic procedures	Same as subject device
Indications for Use	NOTE 1	Same as subject device
Imaging Modes	White Light Near-infrared – fluorescence Near-infrared – transillumination	Same as subject device
Safety Standards	IEC 60601-1 IEC 60601-2-18 IEC 60601-1-2	Same as subject device
Principles of Operation	Via an optical scope and coupler, light is projected onto one or more 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.	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 to3840 x 2160)	Same as subject device
Frame Rate	60 frames per second	Same as subject device
System Components	Camera Control Unit Camera Head(s): Standard, Integrated, and Pendulum Coupler	Camera Control Unit Camera Head(s): Standard & Integrated Coupler

NOTE 1: The 1688 Video Camera is indicated for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery whenever a laparoscope/ endoscope/ arthroscope is indicated for use. 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 surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.

Performance Data:

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

Test	Method/ Rationale	Results
Performance Testing	Locking Knob Actuation Torque Rotating Endobody Torque Pendulum Focus Ring Torque Optical Compliance Coupler Transmission	Pass
Electrical	ANSI AAMI ES60601-1:2005 + A1:2012 IEC 60601-1-6:2010 + A1:2013 IEC 60601-2-18:2009	Pass
EMC	IEC60601-1-2:2014	Pass
Software Verification	IEC 62304:2015	Pass
Cleaning & Disinfection	AAMI TIR 12:2010 AAMI TIR 30:2011 ASTM E2314:2014 ISO 17664:2017	Pass
Sterilization	AAMI TIR 12:2010 AAMI TIR 17:2008 AAMI ST58:2013 AAMI ST77:2013 ISO 17664:2017 ISO 14937:2009	Pass

NOTE: The 1688 4K Camera System does not require clinical studies to support the determination of substantial equivalence.

Conclusions:

The 1688 4K Camera System with Advance Imaging Modality is substantially equivalent in design, intended use, principles of operation, technological characteristics and safety features to the predicate device. There are no new issues of safety and/or effectiveness introduced by the 1688 4K Camera System with Advance Imaging Modality when used as instructed.