February 22, 2024

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

Re: K240174
Trade/Device Name: 1688 4K Camera System with Advanced Imaging Modality
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: January 22, 2024
Received: January 23, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jianting Wang -S

Digitally signed by Jianting Wang -S
Date: 2024.02.22 15:20:10 -05'00'

For Tanisha Hithe
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240174

Device Name

1688 4K Camera System with Advanced Imaging Modality

Indications for Use *(Describe)*

The 1688 4K Camera System with Advanced Imaging Modality 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 4K Camera System with Advanced Imaging Modality is indicated for use in 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, nnee 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 4K Camera System with Advanced Imaging Modality 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.

K240174

510(k) Summary

Prepared on: 2024-02-21

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Stryker Endoscopy
Applicant Address	5900 Optical Court San Jose CA 95138 United States
Applicant Contact Telephone	928-294-9043
Applicant Contact	Mrs. Marlene Fraga
Applicant Contact Email	marlene.fraga@stryker.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	1688 4K Camera System with Advanced Imaging Modality
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
K230216	1688 4K Camera System with Advanced Imaging Modality	GCJ

Device Description Summary

21 CFR 807.92(a)(4)

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 spectrums. 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.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The 1688 4K Camera System with Advanced Imaging Modality 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 4K Camera System with Advanced Imaging Modality is indicated for use in 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, nnee 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.

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Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device, the 1688 4K Camera System with AIM, has the same indications for use and intended use as the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The 1688 4K Camera System with Advanced Imaging Modality (subject device) has the same technological characteristics as the 1688 4K Camera System with Advanced Imaging Modality (predicate device) with the exception of the modifications to the Transition Board which add strength to the board to reduce the likelihood of mechanical damage that may occur through repeated use (i.e. insertion and removal of the camera head cable to the CCU connector).

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 device (1688 4K Camera System with Advanced Imaging Modality System). These include performance bench testing (Camera Head to CCU Connector Insertion and Removal), 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), ANSI AAMI ES 60601-1:2005 + A1:2012 , Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance (FDA recognized voluntary consensus standard: 19-4), 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) and IEC 60601-2-18:2009, Medical electrical equipment – Part 2-18: Particular requirements for the safety of endoscopic equipment (FDA-recognized voluntary consensus standard: 9-114). 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 1688 4K Camera System with Advanced Imaging Modality has the same intended use and indications for use, and fundamental technology as the predicate device. In summary, 1688 4K Camera System with Advanced Imaging Modality is the same or similar with respect to safety and effectiveness to the legally marketed predicate device.