



February 18, 2026

Stryker Endoscopy
Divya Sekar
Senior Principal, Regulatory Affairs Specialist
5900 Optical Ct.
San Jose, California 95138

Re: K260185

Trade/Device Name: 1688 4K Camera System with Advanced Imaging Modality; 1788 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 21, 2026

Received: January 21, 2026

Dear Divya Sekar:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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,

TANISHA Digitally signed by
TANISHA L. HITHE -S
L. HITHE -S Date: 2026.02.18
21:31:02 -05'00'

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K260185

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Please provide the device trade name(s).

?

1688 4K Camera System with Advanced Imaging Modality;
1788 4K Camera System with Advanced Imaging Modality

Please provide your Indications for Use below.

?

1688 Camera 4K Camera System with Advanced Imaging Modality:

The 1688 4K Camera System with Advanced Imaging Modality is indicated for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, neurosurgery, spine surgery, 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 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 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.

1788 Camera 4K Camera System with Advanced Imaging Modality:

The 1788 4K Camera System with Advanced Imaging Modality is indicated for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, neurosurgery, spine surgery, and plastic surgery whenever a laparoscope/ endoscope/arthroscope/ sinuscope is indicated for use. The 1788 4K Camera System with Advanced Imaging Modality is indicated for use in adults and pediatric patients.

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The users of the 1788 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.

Please select the types of uses (select one or both, as applicable).

Prescription Use ([21 CFR 801 Subpart D](#))

Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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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(a).

Submitter:

Applicant:	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138
Contact Person	Divya Sekar Senior Principal, Regulatory Affairs Specialist Email: divya.sekar@stryker.com Phone: 408-754-2473
Date Prepared:	February 6, 2026

Subject Device(s):

Name of Device:	1688 4K Camera System with Advanced Imaging Modality
Common or Usual Name	3-chip Video Camera
Medical Specialty	Gastroenterology & Urology
Regulation Number and Name:	Endoscope and accessories (21 C.F.R. §876.1500)
Regulatory Class:	II
Product Code:	G CJ
Review Panel:	General & Plastic Surgery

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Review Panel:	General & Plastic Surgery

Predicate Device(s):

1688 4K Camera System with Advanced Imaging Modality	K240174
1788 4K Camera System with Advanced Imaging Modality	K233327

Device Description:

Stryker's Advanced Imaging Modality (AIM) System includes the 1688 4K Camera System with AIM and 1788 4K Camera System with AIM, which are endoscopic camera systems that produces live video in the surgical field during surgical endoscopic procedures.

The 1688 4K Camera System with AIM is sensitive in the visible white light 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 1788 4K Camera System with AIM is sensitive in the visible white light, infrared spectrums and short blue 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 and 1788 4K Camera Systems consist 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.

Indications for Use:**1688 Camera 4K Camera System with Advanced Imaging Modality:**

The 1688 4K Camera System with Advanced Imaging Modality is indicated for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, neurosurgery, spine surgery, 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 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 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.

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The users of the 1788 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.

The indications for use statement for the subject devices has been modified from that of the predicate devices to include “spine surgery.” However, this modification does not result in a new intended use, nor does it affect the safety or effectiveness of the device relative to the predicate devices as “spine surgery” is considered a sub-specialty of the previously cleared indication “neurosurgery.” Furthermore, the cleared indications for use for the predicate devices include “laparoscopic and thorascopic anterior spinal fusion” and “decompression fixation,” which are commonly recognized as spine surgeries.

Comparison of Technological Characteristics with Predicate Device(s):

Item	Subject Devices		Predicate Devices	
	1688 4K Camera Systems with Advanced Imaging Modality	1788 4K Camera Systems with Advanced Imaging Modality	1688 4K Camera Systems with Advanced Imaging Modality	1788 4K Camera Systems with Advanced Imaging Modality
Manufacturer	Stryker		Same as subject devices	
Submission Reference	Current submission		K240174	K233327
Intended Use	Endoscopic white light and near-infrared illumination and imaging during endoscopic procedures.		Same as subject devices	
Imaging Modes	<ul style="list-style-type: none"> • White Light • Near-infrared fluorescence • Near-infrared transillumination 	<ul style="list-style-type: none"> • White Light • Near-infrared fluorescence • Near-infrared transillumination • Narrow band illumination 	Same as subject device	Same as subject device

Item	Subject Devices		Predicate Devices	
	1688 4K Camera Systems with Advanced Imaging Modality	1788 4K Camera Systems with Advanced Imaging Modality	1688 4K Camera Systems with Advanced Imaging Modality	1788 4K Camera Systems with Advanced Imaging Modality
Principles of Operations	Via an endoscope 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 devices	
Camera System Components	<ul style="list-style-type: none"> • Camera Control Unit • Camera Head • Coupler 		Same as subject devices	
Safety Standards	<ul style="list-style-type: none"> • IEC 60601-1 • IEC 60601-1-6 • IEC 60601-2-18 • IEC 60601-1-2 • IEC 60601-4-2 		Same as subject devices	
Mode of Operation	<ul style="list-style-type: none"> • Alternate Frame Processing • Simultaneous Frame Processing 		Same as subject devices	
Image Sensor	<ul style="list-style-type: none"> • CMOS image sensor 		Same as subject devices	
Image Processing/ Video Output	<ul style="list-style-type: none"> • Digital 		Same as subject devices	
Resolution	<ul style="list-style-type: none"> • 4K (up to 3840 x 2160) 		Same as subject devices	
Frame Rate	<ul style="list-style-type: none"> • 60 frames per second 		Same as subject devices	
Endoscope Compatibility	<ul style="list-style-type: none"> • Compatible with endoscopes that conform to ISO/TS 18339 		Same as subject devices	

Non-Clinical and/or Clinical Tests Summary & Conclusions:

There were no design changes needed or conducted to support the change in indications for use for the 1688 4K Camera System with AIM and 1788 4K Camera System with AIM. The risk-based assessment demonstrated that the change to specify spine surgery neither introduces new risks nor significantly modifies existing risks including risk score, risk acceptability category, or duration of risk. The overall risk profile remains the same. As such, there was no requirement for additional performance testing. Therefore, we conclude that the 1688 and 1788 4K Camera Systems with AIM are as safe and as effective as the legally marketed predicate devices.