September 20, 2023

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

Re: K231854
Trade/Device Name: 1788 4K Camera System with Advanced Imaging Modality; L12 LED Light Source with AIM
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ, GWG, NWB, OWN, FCS, FCW
Dated: June 23, 2023
Received: June 23, 2023

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,

Tanisha L. Hithe -S
Tanisha L. Hithe -S
2023.09.20
09:19:05 -04'00'

Tanisha Hithe, MS, MHS
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K231854

Device Name
1788 4K Camera System with Advanced Imaging Modality

Indications for Use *(Describe)*

The 1788 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 1788 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, 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 1788 4K Camera System with Advanced Imaging Modality are general and pediatric surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT/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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K231854

Device Name
L12 LED Light Source with Advanced Imaging Modality

Indications for Use *(Describe)*

Upon intravenous administration of SPY AGENT GREEN (indocyanine green for injection, USP), the L12 LED Light Source with Advanced Imaging Modality and SafeLight Cable are used with SPY AGENT GREEN to provide real-time endoscopic visible and near infrared fluorescence imaging. The L12 LED Light Source with Advanced Imaging Modality and SafeLight Cable enable surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion in adults and pediatric patients aged one month and older, and visualization of at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct) in adults and pediatric patients 12 to 17 years of age, using near-infrared imaging.

Fluorescence imaging of biliary ducts with the L12 LED Light Source with Advanced Imaging Modality and SafeLight Cable is intended for use with standard-of-care white light and, when indicated, intraoperative cholangiography. The devices are not intended for standalone use for biliary duct visualization.

Additionally, the L12 LED Light Source with Advanced Imaging Modality and SafeLight Cable enable surgeons to perform minimally invasive cranial neurosurgery in adults and pediatric patients and endonasal skull base surgery in adults and pediatric patients > 6 years of age using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion using near infrared imaging.

Upon interstitial administration of SPY AGENT GREEN, the L12 LED Light Source with Advanced Imaging Modality and SafeLight Cable are used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

Upon administration and use of pafolacianine consistent with its approved label, the L12 LED Light Source with Advanced Imaging Modality and SafeLight™ Cable are used to perform intraoperative fluorescence imaging of tissues that have taken up the drug.

The L12 LED Light Source with Advanced Imaging Modality is also intended to transilluminate the ureter during open or laparoscopic surgical procedures.

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.

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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).

510(k) Number :

Submitter:

Applicant:	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138
Contact Person:	April Malmborg Senior Director, Regulatory Affairs Email: april.malmborg@stryker.com Ph: (408) 754-2472
Date Prepared:	June 23, 2023

Subject Device:

The subject device is the Advanced Imaging Modality (AIM) System and specifically the following system components:

Name of Device:	1788 4K Camera System with Advanced Imaging Modality
Common or Usual Name	3-chip Video Camera
Classification Name:	Endoscope and Accessories (21 C.F.R. §876.1500) Neurological Endoscope (21 C.F.R. §882.1480)
Regulatory Class:	II
Product Code:	GCJ GWG NWB
510(k) Review Panel:	General & Plastic Surgery Neurology Gastroenterology/ Urology

Name of Device:	L12 LED Light Source with AIM
Common or Usual Name	Light Source, Illuminator
Classification Name:	Endoscope and Accessories (21 C.F.R. §876.1500) Fiberoptic light ureteral catheter (21 C.F.R. §876.4020) Neurological Endoscope (21 C.F.R. §882.1480)
Regulatory Class:	II
Product Code:	OWN FCS FCW GWG NWB
510(k) Review Panel:	General & Plastic Surgery Gastroenterology/ Urology Neurology

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Predicate Device(s):

Advanced Imaging Modality (AIM) System	1788 4K Camera System	K230605 (primary)
	L12 LED Light Source	K230754 (primary)
Olympus VISERA ELITE Video System Center and Xenon Light Source		K111425 (secondary)
PINPOINT Endoscopic Fluorescence Imaging System		K182606 (secondary)

Device Description:

Stryker's Advanced Imaging Modality (AIM) System is an endoscopic real-time 4K visible white light, near-infrared illumination and transillumination, and cyan spectral imaging system. Near-infrared illumination is used for fluorescence imaging using SPY AGENT™ GREEN (indocyanine green for injection, USP) or CYTALUX™ (pafalocianine) injection. Near-infrared illumination is also intended for use during transillumination of the ureters using the IRIS Ureteral Kit during minimally invasive and open surgical procedures. Cyan Spectral Imaging is intended as an alternative mode of visualization that uses narrow bands for illumination during endoscopic surgery to provide greater visualization of surface structures and fine capillary patterns of the mucosal membrane.

Indications for Use:

1788 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 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.

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 1788 4K Camera System with Advanced Imaging Modality are general and pediatric surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT/neurosurgeons and urologists.

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L12 LED Light Source with Advanced Imaging Modality:

Upon intravenous administration of SPY AGENT GREEN (indocyanine green for injection, USP), the L12 LED Light Source with Advanced Imaging Modality and SafeLight Cable are used with SPY AGENT GREEN to provide real-time endoscopic visible and near infrared fluorescence imaging. The L12 LED Light Source with Advanced Imaging Modality and SafeLight Cable enable surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion in adults and pediatric patients aged one month and older, and visualization of at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct) in adults and pediatric patients 12 to 17 years of age, using near-infrared imaging.

Fluorescence imaging of biliary ducts with the L12 LED Light Source with Advanced Imaging Modality and SafeLight Cable is intended for use with standard-of-care white light and, when indicated, intraoperative cholangiography. The devices are not intended for standalone use for biliary duct visualization.

Additionally, the L12 LED Light Source with Advanced Imaging Modality and SafeLight Cable enable surgeons to perform minimally invasive cranial neurosurgery in adults and pediatric patients and endonasal skull base surgery in adults and pediatric patients > 6 years of age using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion using near infrared imaging.

Upon interstitial administration of SPY AGENT GREEN, the L12 LED Light Source with Advanced Imaging Modality and SafeLight Cable are used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

Upon administration and use of pafolacianine consistent with its approved label, the L12 LED Light Source with Advanced Imaging Modality and SafeLight™ Cable are used to perform intraoperative fluorescence imaging of tissues that have taken up the drug.

The L12 LED Light Source with Advanced Imaging Modality is also intended to transilluminate the ureter during open or laparoscopic surgical procedures.

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Comparison of Technological Characteristics with the Predicate Device:

Item		Subject Device	Predicate Devices		
			Primary	Secondary	Secondary
		Advanced Imaging Modality (AIM) System	**Advanced Imaging Modality (AIM) System**	**VISERA ELITE**	**PINPOINT System**
Manufacturer		Stryker	Same as subject device	Olympus Medical System Corporation	Same as subject device
Submission Reference(s)		Current Submission	K230605; K230754	K111425	K182606
Intended Use		Endoscopic illumination and imaging during endoscopic procedures	Same as subject device	Same as subject device	Same as subject device
Indications for Use		NOTE 1	Same as subject device	NOTE 2	NOTE 3
System Components		Camera System (subject of submission) Light Source (subject of submission) and SafeLight Cable Endoscopes IRIS Ureteral Kit Imaging Agents	Same as subject device	Video Center Xenon Light Source Videoscope	Video Processor/ Illuminator Camera Head Light Guide Cable Laparoscopes Imaging Agent
Imaging Agents		SPY AGENT GREEN Pafolacianine	Same as subject device	Not applicable.	SPY AGENT GREEN
Principles of Operation		Via an endoscope, light is projected by a light source onto one or more image sensor(s) 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	Same as subject device	Same as subject device
Safety Standards		IEC 60601-1 IEC 60601-2-18 IEC 60601-1-2 IEC 60601-4-2 IEC 60825-1 IEC 62471	IEC 60601-1 IEC 60601-2-18 IEC 60601-1-2 IEC 60601-4-2 IEC 60825-1	IEC 60601-1 IEC 60601-2-18 IEC 60601-2 IEC 62471	IEC 60601-1 IEC 60601-2-18 IEC 60601-2 IEC 60825-1
Imaging Modes	White Light	White Light	Same as subject device	Same as subject device	Same as subject device
	NIR Fluorescence	ENV Contrast Overlay - without IRIS - with IRIS Color Segmented Fluorescence - without IRIS - with IRIS	ENV Contrast Overlay - without IRIS - with IRIS	Not applicable.	Contrast Overlay Color Segmented Fluorescence
	NIR Trans-illumination	IRIS	Same as subject device.	Not applicable.	Not applicable.
	Cyan Spectral Imaging (CSI)	Cyan Spectral Imaging (CSI)	Not Applicable.	Narrow Band Imaging	Not applicable.
Camera System	Image Sensor	CMOS image sensor	Same as subject device.	CCD image sensor	Same as subject device.

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Item		Subject Device	Predicate Devices		
			Primary	Secondary	Secondary
		Advanced Imaging Modality (AIM) System	Advanced Imaging Modality (AIM) System	VISERA ELITE	PINPOINT System
	Image Processing/ Video Output	Digital	Same as subject device.	Same as subject device	Same as subject device.
	Resolution	4K (up to 3840 x 2160) Up to 1920 x 1080	Same as subject device.	Up to 1920 x 1080	Up to 1920 x 1080
	Frame Rate	60 frames per second	Same as subject device.	Same as subject device.	Same as subject device.
Light Source	Light Source/ Laser	RGB LEDs/ Infrared Laser	Same as subject device.	Xenon	Same as subject device.
	Excitation Wavelength	780 nm (used for NIR fluorescence) 830 nm (used for NIR transillumination)	Same as subject device.	Not applicable.	806 nm (used for NIR fluorescence)
	Laser Safety Classification	Class 1M	Same as subject device.	Not applicable.	Class 3R

NOTE 1: The 1788 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 1788 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, 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 1788 4K Camera System with Advanced Imaging Modality are general and pediatric surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT/neurosurgeons and urologists.

Upon intravenous administration of SPY AGENT™ GREEN (indocyanine green for injection, USP), the L12 LED Light Source with AIM and SafeLight™ Cable are used with SPY AGENT GREEN to provide real-time endoscopic visible and near infrared fluorescence imaging. The L12 LED Light Source with AIM and SafeLight Cable enable surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion in adults and pediatric patients aged one month and older, and visualization of at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct) in adults and pediatric patients 12 to 17 years of age, using near-infrared imaging. Fluorescence imaging of biliary ducts with the L12 LED Light Source with AIM and SafeLight Cable is intended for use with standard-of-care white light and, when indicated, intraoperative cholangiography. The devices are not intended for standalone use for biliary duct visualization. Additionally, the L12 LED Light Source with AIM and SafeLight Cable enable surgeons to perform minimally invasive cranial neurosurgery in adults and pediatric patients and endonasal skull base surgery in adults and pediatric patients > 6 years of age using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion using near infrared imaging. Upon interstitial administration of SPY AGENT GREEN, the L12 LED Light Source with AIM and SafeLight Cable is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes. Upon administration and use of pafolacianine consistent with its approved label, the L12 LED Light Source and SafeLight™ Cable is used to perform intraoperative fluorescence imaging of tissues that have taken up the drug. The L12 LED Light Source with AIM is also intended to transilluminate the ureter during open or laparoscopic surgical procedures.

NOTE 2: The video system center has been designed to be used with Olympus cameras heads, endoscopes, light source and monitors, endo-therapy accessories and other ancillary equipment for endoscopic diagnosis, treatment and video observation. The light source has been designed to be used with Olympus endoscopes, video system center, and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

NOTE 3: Upon intravenous administration of SPY AGENT™ GREEN, the PINPOINT Endoscopic Fluorescence Imaging System is used with SPY AGENT GREEN to perform intraoperative fluorescence angiography, and it is also indicated for use in fluorescence imaging of biliary ducts, and when indicated, during intraoperative cholangiography. The PINPOINT Endoscopic Fluorescence Imaging System is indicated for use to provide real time endoscopic visible and near-infrared fluorescence imaging. The PINPOINT System enables surgeons to perform minimally invasive surgery using standard endoscope visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using near infrared imaging. Fluorescence imaging of biliary ducts with the

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PINPOINT System is intended for use with standard of care white light, and when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization. Upon interstitial administration of SPY AGENT GREEN, the PINPOINT System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

Performance Data:

Test	Method	Result
Electromagnetic Compatibility	In accordance with FDA-recognized voluntary consensus standard IEC 60601-1-2:2014 (19-8)	Pass
	In accordance with FDA-recognized voluntary consensus standard IEC 60601-4-2:2016 (19-19)	Pass
Electrical Safety	In accordance with FDA-recognized voluntary consensus standard ANSI AAMI ES 60601-1:2005 + A1:2012 + A2: 2021 (19-46)	Pass
	In accordance with FDA-recognized voluntary consensus standard IEC 60601-1-6:2010 + A1:2013 + A2:2020 (5-132)	Pass
	In accordance with FDA-recognized voluntary consensus standard IEC 60601-2-18:2009 (9-114)	Pass
Laser Safety	In accordance with FDA-recognized voluntary consensus standard IEC 60825-1:2014 (12-273)	Pass
	In accordance with FDA-recognized voluntary consensus standard IEC 62471 (12-249); and, Comparative testing to legally marketed predicate device	Pass
Sterilization	In accordance with FDA-recognized voluntary consensus standard ISO 17664-1:2021 (14-578)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 17664-2:2021 (14-579)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 14937:2009 (14-337)	Pass
	In accordance with AAMI TIR12:2020	Pass
	In accordance with AAMI TIR30:2011	Pass
	In accordance with FDA-recognized voluntary consensus standard AAMI ST58:2013/ (R)2018 (14-432)	Pass
Software Verification and Validation	In accordance with FDA-recognized voluntary consensus standard IEC 62304:2015 (13-79)	Pass
Usability	In accordance with FDA-recognized voluntary consensus standard IEC 62366:2015 + A1:2020 (5-129)	Pass
Performance Testing – Bench	In accordance with device input specifications	Pass
	Comparative testing to currently legally marketed predicate devices: - Spatial Uniformity - Minimum Detectable Fluorescence - Fluorescence Detection Depth - Clinically Meaningful Limits of Detection - Signal to Noise - Photobiological Safety (IEC 62417) - Contrast	Pass
Performance Testing – Animal	In accordance with user needs and intended uses	Pass
	Comparative testing to legally marketed predicate devices	Pass

NOTE: The Advanced Imaging Modality (AIM) System is not patient contacting; therefore, biocompatibility testing was not required to support the determination of substantial equivalence.

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NOTE: The Advanced Imaging Modality (AIM) System does not require clinical studies to support the determination of substantial equivalence.

Conclusions:

The Advanced Imaging Modality (AIM) System is the same or similar in design, intended use, principles of operation, technological characteristics and safety features to the predicate devices. In summary, the Advanced Imaging Modality (AIM) System is the same or similar with respect to safety and effectiveness to the legally marketed predicate devices.