DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 28, 2015

Paragon Medical, Inc.
c/o Mr. Dave Yungvirt, CEO
Third Party Review Group, LLC
45 Rockefeller Plaza, Suite 2000
New York, NY 10111

Re: K152951
Trade/Device Name: Advanced Imaging Modality (AIM) Sterilization Tray
Endoscope and Camera Sterilization Tray
Camera Sterilization Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization wrap
Regulatory Class: II
Product Code: KCT
Dated: November 20, 2015
Received: December 14, 2015

Dear Mr. Yungvirt:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152951

Device Name

Advanced Imaging Modality (AIM) Sterilization Tray
Endoscope and Camera Sterilization Tray
Camera Sterilization Tray

Indications for Use *(Describe)*

The Advanced Imaging Modality (AIM) Sterilization Tray, Endoscope and Camera Sterilization Tray, and Camera Sterilization Tray are intended to enclose and organize Stryker Endoscopy reusable medical instruments during sterilization at a healthcare facility. The trays are optional accessories to the Stryker Endoscopy instruments for which they are designed. The trays are not intended to maintain sterility; they are intended to be used in conjunction with legally marketed, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The Advanced Imaging Modality (AIM) Sterilization Tray, Endoscope and Camera Sterilization Tray, and Camera Sterilization Tray are intended for use in any of the following standard sterilization machines / cycles:

No	Method	Cycle		
1	Ethylene Oxide (EtO)	**Preconditioning Parameters**		
		Temperature (°C)	55°C (131°F)	
		Chamber Humidity	70% RH	
		Vacuum Set Points	1.3 psia	
		Time	30 minutes	
		Exposure		
		Concentration	725 mg/L, 100% EO	
		Temperature (°C)	55°C ±2°C (131°F ±5°F)	
		Time	1 hour	
		Chamber Humidity (%)	70% RH (50-80%) ±5%	
		Aeration		
		Aeration Time	12 hours	
		Temperature	35°C - 54°C (95°F – 129°F)	
2	Prevacuum Steam		**Cycle 1**	**Cycle 2**
		Wrapping	Double	Double
		Temperature	132°C (270°F)	134°C (273°F)
		Sterilization Time	4 minutes	3 minutes
		Dry Time	30 minutes	30 minutes
3	Gravity Steam		**Cycle 1**	**Cycle 2**
		Wrapping	Double	Double
		Temperature	132°C (270°F)	134°C (273°F)
		Sterilization Time	15 minutes	10 minutes
		Dry Time	30 minutes	30 minutes
4	STERIS® V-PRO® 1	Standard		
5	STERIS® V-PRO® 1 Plus	Non-Lumen or Lumen		
6	STERIS® V-PRO® maX	Non-Lumen or Lumen		
7	STERRAD® 100S	Standard		
8	STERRAD® NX®	Standard		
9	STERRAD® 100NX®	Standard		

In addition, the Advanced Imaging Modality (AIM) Sterilization Tray, Endoscope and Camera Sterilization Tray, and Camera Sterilization Tray are validated for the following Immediate Use Steam Sterilization cycles for emergency situations ONLY.

Method	Cycle		
Immediate Use Steam Sterilization ("Flash") Prevacuum Steam		Cycle 1	Cycle 2
	Wrapping	None	None
	Temperature	132°C (270°F)	134°C (273°F)
	Sterilization Time	4 minutes	3 minutes
	Dry Time	None	None

The maximum product loads for the trays are as follows:

Tray Description	Catalog Number	Maximum Tray Product Load	Total Loaded Tray Weight
Advanced Imaging Modality (AIM) Sterilization Tray	0233-032-301	Camera (Qty. 1) Light Cable (Qty. 1) Coupler (Qty. 1) Scope (Qty. 2) Adapter (Qty. 2)	10.58 lbs
Endoscope and Camera Sterilization Tray	233-032-302	Camera (Qty. 1) Light Cable (Qty. 1) Coupler (Qty. 1) Scope (Qty. 2) Adapter (Qty. 2)	10.58 lbs
Camera Sterilization Tray	0233-410-002	Camera (Qty. 1) Light Cable (Qty. 1) Coupler (Qty. 1)	8.83 lbs

* Validated worst case loading configuration included the Advanced Imaging Modality (AIM) Sterilization Tray containing a camera (Qty. 1), light cable (Qty. 1), coupler (Qty. 2), scope (Qty. 3) and adapter (Qty. 3).

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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7 510(k) Summary

Submitter	Paragon Medical 8 Matchett Industrial Park Drive Pierceton, IN 46562
Contact Person	Mike Gosmeyer VP, Quality and Regulatory Paragon Medical, Inc. 8 Matchett Industrial Park Drive Pierceton, IN 46562 Email: mike.gosmeyer@paragonmedical.com Phone: 574-594-2140 ext. 10381
Date Prepared	December 23, 2015
Trade Names	Advanced Imaging Modality (AIM) Sterilization Tray Endoscope and Camera Sterilization Tray Camera Sterilization Tray
Common Name	Sterilization Tray
Classification	21 CFR 880.6850, Sterilization wrap containers, trays, cassettes and other accessories, Class II
Product Code	KCT
Predicate Device	Sterilization cassette by Oticon Medical AB, k141616

Device Description: The Advanced Imaging Modality (AIM) Sterilization Tray, Endoscope and Camera Sterilization Tray, and Camera Sterilization Tray are stainless steel, perforated sterilization trays to allow sterilization gases to penetrate the tray and sterilize the enclosed devices. They are used to enclose and protect particular Stryker endoscopy products during sterilization. The tray is compatible with the following sterilization methods:

- Ethylene Oxide (EtO)
- Prevacuum Steam, Immediate Use Prevacuum Steam, and Gravity Steam
- Steris V-PRO 1 (Standard Cycle), Steris V-PRO 1 Plus (Non-Lumen or Lumen Cycles), Steris V-PRO maX (Non-Lumen or Lumen Cycles)
- STERRAD 100S, STERRAD NX, and STERRAD 100NX (all with Standard Cycle)

The trays are not intended to maintain sterility; they are intended to be used in conjunction with legally marketed, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The trays are comprised of a stainless steel base and removable stainless steel lid. The base includes silicone brackets for Stryker endoscopy device fixation within the tray and two (2) latches to affix the lid to the base. Handles on the sides of the base facilitate carrying of the tray. The trays are reusable and provided in a non-sterile condition.

Intended Use

The Advanced Imaging Modality (AIM) Sterilization Tray, Endoscope and Camera Sterilization Tray, and Camera Sterilization Tray are intended to enclose and organize Stryker Endoscopy reusable medical instruments during sterilization at a healthcare facility. The trays are optional accessories to the Stryker

Endoscopy instruments for which they are designed. The trays are not intended to maintain sterility; they are intended to be used in conjunction with legally marketed, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The Advanced Imaging Modality (AIM) Sterilization Tray, Endoscope and Camera Sterilization Tray, and Camera Sterilization Tray are intended for use in any of the following standard sterilization machines / cycles:

No	Method	Cycle		
1	Ethylene Oxide (EtO)	**Preconditioning Parameters**		
		Temperature (°C)	55°C (131°F)	
		Chamber Humidity	70% RH	
		Vacuum Set Points	1.3 psia	
		Time	30 minutes	
		Exposure		
		Concentration	725 mg/L, 100% EO	
		Temperature (°C)	55°C ±2°C (131°F ±5°F)	
		Time	1 hour	
		Chamber Humidity (%)	70% RH (50-80%) ±5%	
		Aeration		
		Aeration Time	12 hours	
		Temperature	35°C - 54°C (95°F – 129°F)	
2	Prevacuum Steam		**Cycle 1**	**Cycle 2**
		Wrapping	Double	Double
		Temperature	132°C (270°F)	134°C (273°F)
		Sterilization Time	4 minutes	3 minutes
		Dry Time	30 minutes	30 minutes
3	Gravity Steam		**Cycle 1**	**Cycle 2**
		Wrapping	Double	Double
		Temperature	132°C (270°F)	134°C (273°F)
		Sterilization Time	15 minutes	10 minutes
		Dry Time	30 minutes	30 minutes
4	STERIS® V-PRO® 1	Standard		
5	STERIS® V-PRO® 1 Plus	Non-Lumen or Lumen		
6	STERIS® V-PRO® maX	Non-Lumen or Lumen		
7	STERRAD® 100S	Standard		
8	STERRAD® NX®	Standard		
9	STERRAD® 100NX®	Standard		

In addition, the Advanced Imaging Modality (AIM) Sterilization Tray, Endoscope and Camera Sterilization Tray, and Camera Sterilization Tray are validated for the following Immediate Use Steam Sterilization cycles for emergency situations ONLY.

Method	**Cycle**		
Immediate Use Steam Sterilization ("Flash") Prevacuum Steam		**Cycle 1**	**Cycle 2**
	Wrapping	None	None
	Temperature	132°C (270°F)	134°C (273°F)
	Sterilization Time	4 minutes	3 minutes
	Dry Time	None	None

The maximum product loads for the trays are as follows:

Tray Description	**Catalog Number**	**Maximum Tray Product Load**	**Total Loaded Tray Weight**
Advanced Imaging Modality (AIM) Sterilization Tray	0233-032-301	Camera (Qty. 1) Light Cable (Qty. 1) Coupler (Qty. 1) Scope (Qty. 2) Adapter (Qty. 2)	10.58 lbs
Endoscope and Camera Sterilization Tray	233-032-302	Camera (Qty. 1) Light Cable (Qty. 1) Coupler (Qty. 1) Scope (Qty. 2) Adapter (Qty. 2)	10.58 lbs
Camera Sterilization Tray	0233-410-002	Camera (Qty. 1) Light Cable (Qty. 1) Coupler (Qty. 1)	8.83 lbs

* Validated worst case loading configuration included the Advanced Imaging Modality (AIM) Sterilization Tray containing a camera (Qty. 1), light cable (Qty. 1), coupler (Qty. 2), scope (Qty. 3) and adapter (Qty. 3).

Comparison of Intended Use: Relative to the predicate, the indications for use statement for the subject device recommends the following additional sterilization methods: ethylene oxide (EO), gravity steam, immediate use prevacuum steam, Steris V-PRO 1, Steris V-PRO 1 Plus, Steris V-PRO maX, STERRAD 100S, STERRAD NX, and STERRAD 100NX. These new sterilization cycles do not raise new questions of safety and effectiveness and do not affect safety and effectiveness. Performance testing demonstrated the subject device met pre-set acceptance criteria and are substantially equivalent to the predicate. The subject device includes a 30 minute dry time for both the 132°C, 4 minute and 134°C, 3 minute prevacuum steam sterilization cycles. This dry time complies with the recommended 20 to 30 minutes dry times per ANSI/AAMI ST 79:2010 for wrapped instruments. The predicate indicates a shorter 20 minute (132°C, 4 minute) and 16 minute (134°C, 3 minute) prevacuum steam sterilization dry time. The longer dry time of the subject device does not raise new questions of safety and effectiveness and does not affect safety and effectiveness. Performance testing demonstrated the longer dry time of the subject device met pre-set acceptance criteria and is substantially equivalent to the predicate. The subject device has an aeration time of 12 hours at a temperature of 35°C - 54°C (95°F – 129°F) for ethylene oxide (EO) sterilization. The predicate device does not have an aeration time, as it is not indicated for EO sterilization. This aeration time does not raise new questions of safety and effectiveness and does not

affect safety and effectiveness. Performance testing demonstrated that the subject device met pre-set acceptance criteria and is substantially equivalent to the predicate.

The intended use of the subject device is prescription use as compared to over-the-counter (OTC) use for the predicate device. As the subject device is intended to be used with Stryker Endoscopy devices in a clinical setting, its indications for use statement specifies prescription use. This difference does not raise new questions of safety and effectiveness and does not affect safety and effectiveness.

Comparison of Technological Characteristics: Like the predicate device, the subject device is a perforated, stainless steel sterilization tray requiring the usage of an FDA cleared sterilization wrap.

Non-Clinical Testing: The following non-clinical testing was conducted: a) sterilization validations (steam [prevacuum air removal and gravity air displacement cycles], STERRAD [100S, NX, and 100NX], Steris [V-PRO, V-PRO 1 Plus, and V-PRO 1 maX], and Ethylene Oxide (EO)], b) cleaning validations (automated and manual), c) life cycle evaluations of materials and mechanical functionality of latch, d) strength testing of tray handles, and e) latch force testing. All results met acceptance criteria.

Biocompatibility testing was conducted on indirect / secondary patient-contacting materials of the device. Three sets of testing were conducted: 1) presterilization cytotoxicity, 2) presterilization ISO intracutaneous reactivity, and 3) post-sterilization cytotoxicity. Under conditions of the each study, results were as follows: 1) test article extracts showed no cytotoxicity or cell lysis using the grading system of ISO 10993-5, indicating the materials are non-cytotoxic, 2) using the 8-point edema and 4-point erythema scoring system of ISO 10993-10, the overall mean difference in erythema and edema scores scores between control and test articles was 0.0 (0.9% sodium chloride extract) and 0.1 (sesame oil extract), indicating the materials are non-irritating, 3) test article extracts showed grade 2 or less cell lysis and none to mild reactivity, indicating the materials met acceptable cytotoxicity levels (grade 2 or less) post-sterilization.

Clinical Testing: No clinical testing was conducted.

Conclusions: The Advanced Imaging Modality (AIM) Sterilization Tray, Endoscope and Camera Sterilization Tray, and Camera Sterilization Tray have been validated to meet the established performance criteria. Based on the intended use, technological characteristics, performance data, and nonclinical tests performed, the subject devices Advanced Imaging Modality (AIM) Sterilization Tray, Endoscope and Camera Sterilization Tray, and Camera Sterilization Tray are substantially equivalent to, and are safe and as effective as, the legally marketed predicate device, Sterilization Cassette by Oticon Medical AB, under 510(K) K141616.