September 18, 2025

Olympus Medical Systems Corporation
% Brenda Geary
Senior Manager Regulatory Affairs
Olympus Surgical Technologies of the Americas
800 West Park Drive
Westborough, MA 01581

Re: K250883
Trade/Device Name: ULTRASONIC PROBE UM-3R (UM-3R); ULTRASONIC PROBE UM-G20-29R (UM-G20-29R)
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: ITX, ODG
Dated: August 25, 2025
Received: August 25, 2025

Dear Brenda Geary:

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.

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,

MARJAN NABILI -S for

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
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.

K250883

Please provide the device trade name(s).

ULTRASONIC PROBE UM-3R (UM-3R)
ULTRASONIC PROBE UM-G20-29R (UM-G20-29R)

Please provide your Indications for Use below.

The ULTRASONIC PROBE UM-3R has been designed to be used with an Olympus endoscopic ultrasound center, a probe driving unit, other ancillary equipment and an endoscope for intraluminal ultrasonic imaging of the gastrointestinal tract, biliary tract (common bile, cystic, intrahepatic), pancreatic ducts and surrounding organs. This product is intended for use in adults.

[Modes of operation]
The Mode of Operation is B mode.

[Operator qualifications]
Appropriately trained healthcare professionals.

[Device use settings]
Professional healthcare facility (no domestic or special environments)

The ULTRASONIC PROBE UM-G20-29R has been designed to be used with an Olympus endoscopic ultrasound center, a probe driving unit, other ancillary equipment and an endoscope for intraluminal ultrasonic imaging of the gastrointestinal tract, biliary tract (common bile, cystic, intrahepatic), pancreatic ducts and surrounding organs. This product is intended for use in adults.

[Modes of operation]
The Mode of Operation is B mode.

[Operator qualifications]
Appropriately trained healthcare professionals.

[Device use settings]
Professional healthcare facility (no domestic or special environments)

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

☒ Prescription Use (Part 21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary: K250883

1. COMPANY INFORMATION

- **Applicant**

OLYMPUS MEDICAL SYSTEMS CORPORATION
2951 Ishikawa-cho, Hachioji-shi
Tokyo 192-8507, Japan
FDA Establishment Registration #: 8010047

- **Official Correspondent**

Wendy Perreault
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- **Manufacturing Site**

SHIRAKAWA OLYMPUS CO., LTD.
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NISHIGO-MURA
NISHISHIRAKAWA-GUN Fukushima, JAPAN 961-8061

- **Date Prepared:** 18 SEP 2025

2. PRODUCT INFORMATION

Trade Name: ULTRASONIC PROBE UM-3R (UM-3R)
ULTRASONIC PROBE UM-G20-29R (UM-G20-29R)

Common Name: Diagnostic Ultrasound Transducer

Classification Name: Transducer, Ultrasonic, Diagnostic

Classification Number: 892.1570, 876.1500

Product Code Names: Transducer, Ultrasonic Diagnostics; Endoscope and accessories

Product Codes: ITX, ODG

Regulatory Class: II

Classification Panel: Radiology

3. PREDICATE DEVICE

The Subject devices are equivalent to the Predicate device listed below in **Table 1**.

Table 1: Predicate device for ULTRASONIC PROBE UM-3R and UM-G20-29R

Device Name	510(k) Submitter	510(k) No.
Endoscopic Ultrasonic Probe (P2612S-L); Endoscopic Ultrasonic Probe (P2620S-L)	FUJIFILM Corporation	K231666

The Predicate device has not been subject to a design-related recall.

A Reference device was also included for comparison purposes as listed in **Table 2**.

Table 2: Reference device for ULTRASONIC PROBE UM-3R and UM-G20-29R

Device Name	510(k) Submitter	510(k) No.
ULTRASONIC PROBE UM-3R	OLYMPUS MEDICAL SYSTEMS CORPORATION	K063683

4. DEVICE DESCRIPTION

The Ultrasonic Probes have been designed to be used with an Olympus Endoscopic Ultrasound Center, a Probe Driving Unit, other ancillary equipment and an endoscope for intraluminal ultrasonic imaging of the gastrointestinal tract, biliary (common bile, cystic, intrahepatic), pancreatic ducts and surrounding organs.

OLYMPUS Ultrasonic Probes UM-3R and UM-G20-29R are designed to be used in conjunction with gastrointestinal scopes, colonoscopes and duodenoscopes. The Probes are inserted into the patient through a channel of the endoscope.

The Ultrasonic Probes consist of an insertion tube and a connector section. The connector section is connected to the Probe Driving Unit and the Probe Driving Unit is connected to the Ultrasound Center.

The Ultrasonic Probe sends and receives electrical signals to and from the Ultrasound Center

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through the Probe Driving Unit. The Probes use a 20MHz frequency piezoelectric transducer and produce B-mode scan. They produce 360-degree mechanical/radial sonograms.

The transducer is built into the insertion tube at the tip of the Probe. The transducer is rotated by the Probe Driving Unit within the insertion tube.

The transducer converts the electrical signal to the ultrasound wave, sends it to the object, receives the reflected wave from the object and converts it to the electrical signal. The electrical signal is input to the Endoscopic Ultrasound Center and the ultrasound image is generated by the Endoscopic Ultrasound Center.

UM-3R is used with the direct contact method and the sterile de-aerated water immersion method. UM-G20-29R is used with the direct contact method only.

The Subject devices submitted for clearance each include one (1) major component: the Ultrasonic Probe, which is packaged with a Probe Holder (MH-245) and a Water-resistant Cap (MH-244).

5. INDICATIONS FOR USE

For UM-3R:

The ULTRASONIC PROBE UM-3R has been designed to be used with an Olympus endoscopic ultrasound center, a probe driving unit, other ancillary equipment and an endoscope for intraluminal ultrasonic imaging of the gastrointestinal tract, biliary tract (common bile, cystic, intrahepatic), pancreatic ducts and surrounding organs. This product is intended for use in adults.

[Modes of operation]
The Mode of Operation is B mode.

[Operator qualifications]
Appropriately trained healthcare professionals.

[Device use settings]
Professional healthcare facility (no domestic or special environments)

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For UM-G20-29R:

The ULTRASONIC PROBE UM-G20-29R has been designed to be used with an Olympus endoscopic ultrasound center, a probe driving unit, other ancillary equipment and an endoscope for intraluminal ultrasonic imaging of the gastrointestinal tract, biliary tract (common bile, cystic, intrahepatic), pancreatic ducts and surrounding organs. This product is intended for use in adults.

[Modes of operation]
The Mode of Operation is B mode.

[Operator qualifications]
Appropriately trained healthcare professionals.

[Device use settings]
Professional healthcare facility (no domestic or special environments)

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Compared to the Predicate device, the Subject devices offer similar functions. A detailed comparison of the technological characteristics of the devices is provided in **Table 3** below. These differences in technological characteristics do not raise new questions of safety or effectiveness.

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Table 3: Subject and Predicate Comparison of Technological Characteristics

Item	Subject Devices (SD)		Predicate Device (PD)	Reference Device (RD)	Comparison
	UM-3R	UM-G20-29R	FUJIFILM Endoscopic Ultrasonic Probe (P2612S-L); Endoscopic Ultrasonic Probe (P2620S-L)	UM-3R	
Indications for Use	The ULTRASONIC PROBE UM-3R has been designed to be used with an Olympus endoscopic ultrasound center, a probe driving unit, other ancillary equipment and an endoscope for intraluminal ultrasonic imaging of the gastrointestinal tract, biliary tract (common bile, cystic, intrahepatic), pancreatic ducts and surrounding organs. This product is intended for use in adults. [Modes of operation] The Mode of Operation is B mode. [Operator qualifications] Appropriately trained healthcare professionals. [Device use settings] Professional healthcare facility (no domestic or special environments)	The ULTRASONIC PROBE UM-G20-29R has been designed to be used with an Olympus endoscopic ultrasound center, a probe driving unit, other ancillary equipment and an endoscope for intraluminal ultrasonic imaging of the gastrointestinal tract, biliary tract (common bile, cystic, intrahepatic), pancreatic ducts and surrounding organs. This product is intended for use in adults. [Modes of operation] The Mode of Operation is B mode. [Operator qualifications] Appropriately trained healthcare professionals. [Device use settings] Professional healthcare facility (no domestic or special environments)	This product is a medical ultrasonic probe. It is intended for the observation and diagnosis of the gastrointestinal tract and surrounding organs under the management of physicians at medical facilities. This product is intended for adults. Modes of Operation: B-mode Never use this product for any other purposes.	These instruments have been designed to be used with an Olympus Endoscopic Ultrasound Center, a Water Supply Unit (For Ultrasonic Endoscope), a Probe Driving Unit, a Probe/Irrigation Plug and an endoscope for intralumenal ultrasonic imaging of the gastrointestinal tract and surrounding organs, the upper airways and tracheobronchial tree and the urinary organs.	• Similar to PD; SDs specifically include use in biliary tract and pancreatic ducts. • RD included indication for use with the upper airways and tracheobronchial tree and the urinary organs. Similar OLYMPUS Ultrasonic Probes (UM-S20-17S and UM-S20-20R) were cleared under K250762 for use in the upper respiratory tract; the indications for use in urinary organs are no longer included for business reasons. • RD indication called out the Water Supply Unit and the Probe/Irrigation Plug, which are no longer called out specifically in the SD Indications for Use but are considered covered under the newly added text “other ancillary equipment.”

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Item	Subject Devices (SD)		Predicate Device (PD)	Reference Device (RD)	Comparison
	UM-3R	UM-G20-29R	FUJIFILM Endoscopic Ultrasonic Probe (P2612S-L); Endoscopic Ultrasonic Probe (P2620S-L)	UM-3R	
Frequency	20 MHz	20 MHz	P2612S-L: 10MHz±15% P2620S-L: 17MHz±15%	20 MHz	Similar to PD; same as RD. Although the frequency is not identical to the PD, performance of the SD will be confirmed through electrical safety, EMC and performance testing.
Display mode	B-mode	B-mode	B-mode	B-mode	Same as RD and PD.
Compatible Endoscopic Ultrasound System	EU-ME2 EU-ME2 Premier Plus EU-ME3	EU-ME2 EU-ME2 Premier Plus EU-ME3	FUJIFILM Ultrasonic Processor SP-900	XEU-M60A	Different; although the compatible Endoscopic Ultrasound System is not shared between the Subject devices and the PD (or RD), the compatibility with the listed Endoscopic Ultrasound Systems will be verified in terms of accuracy of ultrasound performance, acoustic output, EMC and electrical safety.
Compatible Endoscopes	Gastrointestinal scope, colonoscope and duodenoscope with working length (maximum) of 1330mm and instrument channel diameter (minimum) 2.8mm.	Gastrointestinal scope, colonoscope and duodenoscope with working length (maximum) of 1330mm and instrument channel diameter (minimum) 3.2mm.	FUJIFILM endoscope • Upper gastrointestinal • Lower gastrointestinal *The instrument channel of each endoscope must be 2.8mm or more and its working length 2200mm or less. *This product is not applied in combination with Duodenoscope and Ultrasonic endoscope	Except L-length Colonoscope Channel Inner Diameter (mm): 2.8, 3.2, 3.7, 4.2, 5.5 Gastrointestinal scope with instrument channel diameter minimum 2.8mm or instrument channel capacity minimum 9 Fr. Gastrointestinal scope with instrument channel diameter minimum 3.7mm or instrument channel capacity minimum 12 Fr.	Similar to PD; SDs also allow use with compatible colonoscopes and duodenoscopes. Similar to RD.
Number of Transducers	1	1	*Information not available in 510(k) Summary*	1	Same as RD.

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Item	Subject Devices (SD)		Predicate Device (PD)	Reference Device (RD)	Comparison
	UM-3R	UM-G20-29R	FUJIFILM Endoscopic Ultrasonic Probe (P2612S-L); Endoscopic Ultrasonic Probe (P2620S-L)	UM-3R	
Shape of Transducer	Rectangle	Rectangle	*Information not available in 510(k) Summary*	Rectangle	Same as RD.
Size of Transducer	1.55 x 2.3mm	1.2 × 2.3mm	*Information not available in 510(k) Summary*	1.6 × 2.4mm	Different from RD; although the size of the Transducer is different between the Subject devices and the PD, the accuracy of ultrasound performance and acoustic output for the Subject Transducers will be verified.
Guide Wire port	No	Yes *Guidewires up to 0.035" may be used*	No	No	The Subject UM-3R and PD and RD are not used with a Guide Wire and therefore do not have Guide Wire ports. The UM-G20-29R will be manufactured to be used with a Guide Wire; its Guide Wire port is located on the Insertion Tube and is the same material as the insertion portion.
Scanning direction	Perpendicular to the direction of insertion	Perpendicular to the direction of insertion	*Information not available in 510(k) Summary*	Perpendicular to the direction of insertion	Same as RD.
Scanning field of view (Scanning area)	360°	360°	*Information not available in 510(k) Summary*	360°	Same as RD.
Frame rate	6.67rps	6.67rps	*Information not available in 510(k) Summary*	6.67rps	Same as RD.
xial resolution	2mm or less	2mm or less	1mm or less	2mm or less	Same as RD, different from PD. Although the axial resolution is not identical to the PD, performance of the SD will be confirmed through electrical safety, EMC and performance testing.

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Item	Subject Devices (SD)		Predicate Device (PD)	Reference Device (RD)	Comparison
	UM-3R	UM-G20-29R	FUJIFILM Endoscopic Ultrasonic Probe (P2612S-L); Endoscopic Ultrasonic Probe (P2620S-L)	UM-3R	
Lateral resolution	2mm or less	2mm or less	3mm or less	2mm or less	Same as RD; different from PD. Although the lateral resolution is not identical to the PD, performance of the SD will be confirmed through electrical safety, EMC and performance testing.
Scanning method	Mechanical, radial scanning	Mechanical, radial scanning	Mechanical, radial scanning	Mechanical, radial scanning	Same as PD and RD.
Contact method	Direct contact method	Direct contact method	*Information not available in 510(k) Summary*	Direct contact method	Same as RD; different from PD, but penetration of SDs is between penetration of two PD models. Although the penetration is not identical to the PD, performance of the SD will be confirmed through electrical safety, EMC and performance testing.
	Sterile De-aerated water immersion method	N/A		Sterile De-aerated water immersion method	Same for UM-3R and RD. UM-G20-29R is intended for use with a Guide Wire in the biliary and pancreatic ducts, and therefore the sterile De-aerated water immersion method (sometimes used with Ultrasonic Probes in larger organs) is not applicable and is not described in the device Instructions for Use.

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Item	Subject Devices (SD)		Predicate Device (PD)	Reference Device (RD)	Comparison
	UM-3R	UM-G20-29R	FUJIFILM Endoscopic Ultrasonic Probe (P2612S-L); Endoscopic Ultrasonic Probe (P2620S-L)	UM-3R	
	N/A	N/A		Balloon method (Balloon sheath [MH-246R] is necessary).	Different than RD. Ultrasonic imaging by the balloon method is not applicable to the SDs and is not described in the devices' Instructions for Use. For UM-G20-29R, this ultrasonic probe is designed to be used with a Guide Wire. The Balloon and Guide Wire cannot be used simultaneously. For UM-3R, the direct contact method is applicable to its use in organs in a small space and the sterile de-aerated water immersion method is applicable for use in organs in a large space.
Insertion tube maximum outer diameter (mm)	ϕ 2.55	ϕ 2.9 (Incl. Guidewire port) ϕ 2.25 (Excl. Guidewire port)	2.6mm	ϕ 2.5	Similar to PD and RD. The differences are not significant, and performance of the SD will be confirmed through electrical safety, EMC and performance testing.
Insertion tube outer diameter (mm)	ϕ 2.5	ϕ 2.2	2.5mm	ϕ 2.4	
Ultrasonic medium	Liquid paraffin (High White 70)	Liquid paraffin (High White 70)	*Information not available in 510(k) Summary*	Liquid paraffin (High White 70)	Same as RD.
Working length (mm)	2050	2050	2620	2050	Shorter than PD; difference does not affect safety and efficacy. Same as RD. Performance of the SD will be confirmed through electrical safety, EMC and performance testing.

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Item	Subject Devices (SD)		Predicate Device (PD)	Reference Device (RD)	Comparison
	UM-3R	UM-G20-29R	FUJIFILM Endoscopic Ultrasonic Probe (P2612S-L); Endoscopic Ultrasonic Probe (P2620S-L)	UM-3R	
Total length (mm)	2140	2140	*Information not available in 510(k) Summary*	2140	Same as RD.
Sterilization method for reprocessing	ETO	ETO	ETO	N/A	Same as PD, different for RD; reprocessing validation testing will be conducted to confirm compatibility with the sterilization method for the Subject devices.
Compatible Olympus Reprocessor for cleaning and disinfection	OER-Pro OER-Elite	OER-Pro OER-Elite	N/A	N/A	Different from RD and PD; compatibility of the SDs with the Olympus Reprocessors was confirmed with reprocessing validations.
Electrical safety	Compliance to IEC 60601-1, IEC 60601-2-18, IEC 60601-2-37	Compliance to IEC 60601-1, IEC 60601-2-18, IEC 60601-2-37	Compliance to IEC 60601-1, IEC 60601-2-37	Compliance to IEC 60601-1, IEC 60601-2-18	Equivalent to PD and RD.
EMC	Compliance to IEC 60601-1-2	Compliance to IEC 60601-1-2	Compliance to IEC 60601-1-2	Compliance to IEC 60601-1-2	Same as PD and RD.

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7. SUMMARY OF NON-CLINICAL PERFORMANCE DATA

Results of the following testing support the safety and performance of the Subject devices and demonstrate their equivalence to the Predicate device; all testing passed/met the acceptance criteria, demonstrated compliance with the cited standards and FDA Guidance shown below, and supported equivalent safety and performance to the Predicate device:

- Performance Testing – Bench (including Acoustic Output in compliance with IEC 60601-2-37, IEC 62359, IEC 62127-1, and FDA Guidance: *Marketing Clearance of Diagnostic Ultrasound Systems and Transducers - Guidance for Industry and Food and Drug Administration Staff* (February 21, 2023); Durability, Measurement Accuracy; and Human Use Factors following FDA Guidance Documents *Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff* (issued February 3, 2016) and *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff* (issued March 17, 2015).
- Biocompatibility Testing (ISO 10993-1; ISO 10993-5; ISO 10993-10; ISO 10993-12; ISO 10993-17; ISO 10993-18; ISO 10993-23)
- Reprocessing Validation (ISO 17644-1; AAMI TIR12; ANSI AAMI ST98; ANSI AAMI ST58; ISO 11135; ISO11138-2)
- Electrical Safety/EMC Testing (IEC 60601-1; IEC ES60601-1; IEC 60601-1-2; IEC 60601-2-18; IEC 60601-2-37; IEC TR 60601-4-2)

8. SUMMARY OF CLINICAL PERFORMANCE DATA

No clinical data were collected to support the performance of the Subject devices.

9. CONCLUSION

The results of non-clinical performance testing demonstrate that the Subject devices are as safe and effective as the Predicate device to support a substantial equivalence determination.