DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 28, 2017

Custom Ultrasonics Inc.
Elizabeth Lazaro
Regulatory Affairs Director
144 Railroad Drive
Ivyland, Pennsylvania 18974

Re: K162120
Trade/Device Name: Scope-Assist Flushing Sink
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FEB
Dated: March 28, 2017
Received: March 29, 2017

Dear Elizabeth Lazaro:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting 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)*
K162120

Device Name
Scope-Assist Flushing Sink

Indications for Use *(Describe)*

The Scope-Assist Flushing Sink is indicated for flushing the channels of flexible endoscopes according to the endoscope manufacturer's instructions.

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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K162120

510(k) Summary of Substantial Equivalence of Safety and Efficacy

Submitter: Custom Ultrasonics Inc.

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Ivyland, PA 18974

Telephone: 215-364-1477

Contact Person: Elizabeth Lazaro
Title: Regulatory Affairs Director
e-mail: *elizabeth.lazaro@customultrasonics.com*

Date Prepared: April 19, 2017
Name of Device: Scope-Assist Flushing Sink

Classification Name: Endoscope and accessories

Product Code: FEB

Regulation: 21 CFR 876.1500

Device Classification: Class II

Predicate Device: PSK System (K000216)

Indications for Use: The Scope-Assist Flushing Sink is indicated for flushing the channels of flexible endoscopes according to the endoscope manufacturer's instructions.

Device Description: The Scope-Assist Flushing Sink is designed to mechanically assist the channel flushing portion of an endoscope's manual cleaning process. The sink facilitates compliance with endoscope manufacturer's cleaning requirements by:

- Providing a means of flushing flexible endoscope channels with detergent solution
- Providing a means of flushing endoscope channels with water
- Providing an environment for soaking and manual wiping/brushing of flexible endoscope exterior surfaces and accessories
- Providing an environment to perform wet leak testing of

  endoscopes The Scope-Assist Flushing Sink is designed:
- To be used where the facility performs its endoscope cleaning functions, such as in soiled utility rooms, central processing decontamination areas, or endoscope cleaning (reprocessing) areas.
- To be used with Tergal 800 Detergent

The Scope-Assist Flushing Sink is **not** designed:

- To be used at bedside, in critical care units, or in sterile environments
- To be used as a terminal process or as part of the manual high level disinfection process

Performance Data: Performance testing conducted with the Scope-Assist Flushing Sink:

- Flushing performance testing to demonstrate the device is able to meet or exceed the endoscope manufacturer's flushing requirements in the specified flushing times.
- Detergent Injection testing to demonstrate the device is able to consistently and reliably deliver the correct amount of detergent.
- Detergent Compatibility testing to demonstrate the use of Tergal detergent is compatible with the materials in the flow path of the sink.
- Electrical safety testing according to IEC 61010-1
- Electromagnetic compatibility testing according to IEC 60601-1-2

Equivalency: The Scope-Assist Flushing Sink is equivalent to the PSK System for flushing liquids through various channels of a flexible endoscope.

Substantial Equivalence Table			
Trade Name	***Scope-Assist Flushing Sink***	***PSK System***	
Device Parameters	**Subject Device**	**Predicate Device**	**Equivalence**
Intended Use:	Flush the channels of flexible endoscopes	Flush the channels of flexible endoscopes	Same
Technological Characteristics:	Pump used to deliver fluids through endoscope's internal channels	Pump used to deliver fluids through endoscope's internal channels	Same
	Ability to flush all channels simultaneously	Ability to flush all channels simultaneously	Same
Endoscope Processing Capacity:	(1)	(1)	Same
Connector Tubing:	Color coded endoscope specific adapters used to connect scope to flushing source	Color coded endoscope specific adapters used to connect scope to flushing source	Same
Water Source:	Potable tap water	Potable tap water	Same
Amount of Fluid Delivered:	Amount sufficient to meet or exceed the endoscope manufacturer's requirements for volume of fluid delivery through endoscope channels	Amount sufficient to meet or exceed the endoscope manufacturer's requirements for volume of fluid delivery through endoscope channels	Same
Time for Fluid Circulation:	Variable, the length of the fluid circulation time is sufficient to deliver fluid volumes that meet or exceed the endoscope manufacturer's requirements	Variable, the length of the fluid circulation time is sufficient to deliver fluid volumes that meet or exceed the endoscope manufacturer's requirements	Same

Conclusion:

Based on the intended use and performance testing data, the Scope-Assist Flushing Sink meets the requirements for flushing the internal channels of a flexible endoscope and is substantially equivalent to the predicate device. In addition, the Scope-Assist Flushing Sink, as demonstrated by electrical safety and electromagnetic compatibility testing, demonstrates substantial equivalence.