March 30, 2020

Custom Ultrasonics, Inc.
Mario Infanti
Quality Assurance Manager
144 Railroad Drive
Ivyland, Pennsylvania 18974

Re: K173590
Trade/Device Name: System 83 Plus Washer/Disinfector
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FEB
Dated: December 17, 2019
Received: December 6, 2017

Dear Mario Infanti:

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,

CAPT Elizabeth Claverie, M.S.
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K173590

Device Name
System 83 Plus™ Washer/Disinfector

Indications for Use *(Describe)*
System 83 Plus™ Washer/Disinfector is designed for the simultaneous high level disinfection of up to two flexible submersible endoscopes that are used in the gastrointestinal and/or pulmonary tracts. Flexible endoscopes that are pre-cleaned and manually cleaned, and then exposed to the washing /disinfection cycle of the System 83 Plu s™, may be high level disinfected when the disinfection cycle corresponds to the System 83 Plus™ validated contact conditions of the high level disinfectant.

Note: The System 83 Plus™ device includes two models.
• The System 83 Plus™ 2 has one processing chamber that can process 1 to 2 flexible endoscopes at a time .
• The System 83 Plus™ 9 has two processing chambers that can process 1 to 2 flexible endoscopes at a time in each independently operated processing chamber for a total of up to 4 endoscopes simultaneously.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary
# K173590

**1. 510(k) Submitter**

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**Fax:** (215) 364-7674

**Contact Person:** Mario Infanti
Quality Assurance Manager
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**Email:** mario.infanti@customultrasonics.com

**Date Prepared:** March 20, 2020

**2. Device**

**Trade Name:** System 83 Plus™ Washer/Disinfector
**Common Name:** Automated Endoscope Reprocessor
**Classification Name:** Endoscope and accessories (21 CFR § 876.1500)
**Regulatory Class:** II
**Product Code:** FEB

**3. Predicate Device**

Custom Ultrasonics, Inc., System 83 Plus™ Endoscope Washer/Disinfector, K122172

**4. Device Description**

The System 83 Plus™ is an automated, computer controlled, electro-mechanical system intended to wash and high-level disinfect one or two submersible flexible endoscopes (per bay) utilizing a detergent and FDA cleared high-level disinfectant validated by CUI. The System 83 Plus™ device family includes two models. The System 83 Plus™ 2; a model with one processing chamber, which can process one to two flexible endoscopes at a time. The System 83 Plus™ 9: a model with two processing chambers which can asynchronously reprocess up to 2 endoscopes per bay (total of up to 4 endoscopes).

The System 83 Plus™ utilizes a processing chamber and the immersion method to perform washing, disinfection, rinsing, and alcohol flush of an endoscope to render a high level disinfected endoscope. The System 83 Plus™ is capable of automated detergent dispensing and transfer of disinfectant solution between the reservoir and processing chamber. Following disinfection, the endoscopes and channels are automatically rinsed with potable water that is filtered through a water filtration system that contains a 0.1 micron bacteria filter and the channels are then flushed with air. A semi-automated air/alcohol flush must be completed at the end of the cycle. At completion, the operator prints out the endoscope reprocessing information with a printer.

Built-in sensors detect fluid levels, fluid temperature, fluid flow, and the operating states of the components within System 83 Plus™.

**5. Indications for Use**

System 83 Plus™ Washer/Disinfector is designed for the simultaneous high level disinfection of up to two flexible submersible endoscopes that are used in the gastrointestinal and/or pulmonary tracts.

Flexible endoscopes that are pre-cleaned and manually cleaned, and then exposed to the washing/disinfection cycle of the System 83 Plus™, may be high level disinfected when the disinfection cycle corresponds to the System 83 Plus™ validated contact conditions of the high level disinfectant.

Note: The System 83 Plus™ device includes two models.

- The System 83 Plus™ 2 has one processing chamber that can process 1 to 2 flexible endoscopes at a time.
- The System 83 Plus™ 9 has two processing chambers that can process 1 to 2 flexible endoscopes at a time in each independently operated processing chamber for a total of up to 4 endoscopes simultaneously.

**6. Summary of Technological Characteristics Compared to the Predicate Device**

The System 83 Plus™ has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device, except for the following primary difference is the System 83 Plus device has been validated for use with *ortho*-Phthalaldehyde Solution high-level disinfectant (OPA) with a nominal active ingredient composition of 0.55%, having a Minimum Recommended Concentration (MRC) of 0.3%, minimum contact condition of 12 minutes at 20°C, and a re-use period not to exceed 14 days.

See **Table 1:** Technical Characteristics

**Table 1:** Technical Characteristics

| Features | Predicate Device: K122172 | Subject Device: K173590 | Comments on Difference |
|---|---|---|---|
| **Intended Use** | The System 83 Plus is designed for the simultaneous reprocessing of up to two flexible submersible endoscopes that are used in the gastrointestinal and/or pulmonary tracts. Flexible scopes that are precleaned and then exposed to the washing / disinfection cycle of the System 83 Plus™ may be high-level disinfected when the disinfection cycle corresponds to the labeled contact conditions for the germicide as in the predicated.<br><br>Note: The System 83 Plus™ device includes two models.<br>• The System 83 Plus™ 2 is a device with one processing chamber that can process 1 to 2 flexible endoscopes at a time.<br>• The System 83 Plus™ 9 is two 'System 83 Plus™ 2' units put together. It has two processing chambers which can process 1 to 2 flexible endoscopes in each independently operated processing chamber. | System 83 Plus™ Washer/Disinfector is designed for the simultaneous high level disinfection of up to two flexible submersible endoscopes that are used in the gastrointestinal and/or pulmonary tracts. Flexible endoscopes that are pre-cleaned and manually cleaned, and then exposed to the washing/disinfection cycle of the System 83 Plus™, may be high level disinfected when the disinfection cycle corresponds to the System 83 Plus™ validated contact conditions of the high level disinfectant.<br><br>Note: The System 83 Plus™ device includes two models.<br>• The System 83 Plus™ 2 has one processing chamber that can process 1 to 2 flexible endoscopes at a time.<br>• The System 83 Plus™ 9 has two processing chambers that can process 1 to 2 flexible endoscopes at a time in each independently operated processing chamber for a total of up to 4 endoscopes simultaneously. | The underlined expression is modified; however, the substantive content remains the same. |
| **Disinfectant** | Various glutaraldehyde, OPA, and hydrogen peroxide solutions | *Ortho*-Phthalaldehyde Solution high-level disinfectants (OPA) with a nominal active ingredient composition of 0.55%, having a Minimum Recommended Concentration (MRC) of 0.3% | Currently, the System 83 Plus is only validated with *Ortho*-Phthalaldehyde (OPA) Solution high-level disinfectants |
| **Detergent** | Tergal 800® detergent | Tergal 800® detergent | None |
| **High Level Disinfect Method** | Exterior surfaces immersion in disinfectant solution and channel interior flushing of disinfectant solution | Same as the predicate device | None |
| **Ultrasonics Detection** | Audibly determine if ultrasonics are working by listening for a distinct buzzing sound | Ultrasonic Abort – A feature in software version 1.0.15 that indicates if the ultrasonics are not functioning during reprocessing – The operator is alerted and the system process is aborted. | Software Validation testing and risk analysis was conducted to validate the modification. As a result, this modification does not affect the safety and effectiveness of the subject device. |

## 7. Summary of Non-Clinical Testing

Performance testing was conducted to satisfy the requirement for the System 83 Plus™ Washer/Disinfector , as outlined in the Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities (August 1993). This testing is summarized in the following Table.

| Performance Testing | Description | Acceptance Criteria | Pass / Fail |
|---|---|---|---|
| Simulated use testing | High-level disinfection validation of representative worst case endoscopes under worst case simulated use conditions | ≥6 Log reduction of *M.terrae* at all inoculated sites | Pass |
| In-use testing | High-level disinfection validation of representative worst case endoscopes and valves under in-use conditions | <1 CFU at all processed test sites | Pass |
| Alcohol and detergent line disinfection | Disinfection of the alcohol and detergent injection lines | ≥6 Log reduction of *M.terrae* | Pass |
| Toxicological evaluation of residues and rinsing validation | The safety of residual chemicals remaining on endoscopes after high level disinfection was evaluated. The testing was conducted in accordance with ISO 10993-5:2009 | Reactivity grade of 2 or less | Pass |
| Channel volume flushing | Flushing validation testing of representative worst case endoscopes under worst case simulated use conditions | Satisfy endoscope manufacturer's manual flushing requirements | Pass |
| Water filtration system validation | Validation testing under worst case simulated use conditions | <10 CFU per 100 mL | Pass |
| In-line Disc filter validation | Validation testing under worst case simulated use conditions | ≥99% efficient at removing particles ≥250µm | Pass |

Electrical safety testing:
Electrical safety testing was conducted. The system complies with the UL 60601-1:2003 standard for safety.

Electromagnetic compatibility testing:
EMC testing was conducted. The system complies with the IEC 60601-1-2:2001 + A1:2004 standard for EMC.

Software verification and validation testing:
Software verification and validation testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

## 8. Conclusion

Based on the intended use, technological characteristics, and performance data, the System 83 Plus Washer/Disinfector is as safe, as effective, and performs as well as or better than the legally marketed predicate device (K122172).