December 19, 2024

Wassenburg Medical, Inc.
Mario Infanti
Quality Assurance and Regulatory Affairs Manager
144 Railroad Drive
Ivyland, Pennsylvania 18974

Re: K241168
Trade/Device Name: System 83 Revolve® Endoscope Washer/Disinfector
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FEB
Dated: June 06, 2024
Received: November 26, 2024

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 (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,

Katharine Segars -S

Katharine Segars, Ph.D.
Assistant Director
DHT4C: Division of Infection Control
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Infection Control Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241168

Device Name
System 83 Revolve® Endoscope Washer/Disinfector

Indications for Use *(Describe)*
The System 83 Revolve® Endoscope Washer/Disinfector is designed for the high-level disinfection of one or two flexible submersible endoscopes that are used in the gastrointestinal and pulmonary tracts. Flexible endoscopes that undergo bedside cleaning, are manually cleaned, and then exposed to the wash/disinfect cycle of the System 83 Revolve® may be high-level disinfected when the validated disinfection cycle of the System 83 Revolve® corresponds with the labeled contact conditions of the high-level disinfectant.

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.

510(k) Summary
K241168

510(k) Submitter/Owner

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Contact Person: Mario Infanti
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Date Prepared: December 19, 2024

Subject Device

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

Predicate Device

Wassenburg Medical, Inc., System 83 Plus Endoscope Washer/Disinfector, K173590

Device Description

The System 83 Revolve® Endoscope Washer/Disinfector is an automated, computer controlled, electro-mechanical system intended to wash and high-level disinfect one or two submersible flexible endoscopes utilizing a detergent and FDA cleared high-level disinfectant validated by Wassenburg Medical.

The System 83 Revolve® 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 Revolve® 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 Revolve®. The system contains a Touchscreen (Graphical User Interface), a Barcode Scanner, an LED Indicator Strip that displays the process status, and a reprocessing chamber lid operation that is hands free.

Indication for Use

The System 83 Revolve® Endoscope Washer/Disinfector is designed for the high-level disinfection of one or two flexible submersible endoscopes that are used in the gastrointestinal and pulmonary tracts. Flexible endoscopes that undergo bedside cleaning, are manually cleaned, and then exposed to the wash/disinfect cycle of the System 83 Revolve® may be high-level disinfected when the validated disinfection cycle of the System 83 Revolve® corresponds with the labeled contact conditions of the high-level disinfectant.

Summary of Technological Characteristics Compared to the Predicate Device

The subject and the predicate device have the same technological elements.

- Washer / Disinfector
- Operator and Software controlled processes
- 120 VAC Energy Source
- Materials

Technological Characteristic Comparison

The following table compares the subject device to the predicate device with respect to intended use, indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence.

Table 1. Predicate Device Comparison Table

Feature	Subject Wassenburg Medical, Inc. System 83 Revolve	Predicate (K173590) Wassenburg Medical, Inc. System 83 Plus	Comparison
Indications for Use	The System 83 Revolve® Endoscope Washer/Disinfector is designed for the high-level disinfection of one or two flexible submersible endoscopes that are used in the gastrointestinal and pulmonary tracts. Flexible endoscopes that undergo bedside cleaning, are manually cleaned, and then exposed to the wash/disinfect cycle of the System 83 Revolve® may be high-level disinfected when the validated disinfection cycle of the System 83 Revolve® corresponds with the labeled contact conditions of the high-level disinfectant.	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.	Similar; however, the note is not applicable for two models, because there is only a single model, similar to the System 83 Plus 2.
Intended Use	Washing and high-level disinfection of one or two submersible flexible endoscopes	Washing and high-level disinfection of one or two submersible flexible endoscopes	Identical.

Feature	Subject Wassenburg Medical, Inc. System 83 Revolve®	Predicate (K173590) Wassenburg Medical, Inc. System 83 Plus	Comparison
Operating Principles / Technology	• The System 83 Revolve is a microprocessor controlled device that provides delivery of solutions and fluids to the endoscope, endoscope channels, and accessories. Tergal 800 detergent and *Ortho*-Phthalaldehyde Solution high-level disinfectants (OPA) are utilized to provide high level disinfection of an endoscope and accessories.	• The System 83 Revolve is a microprocessor controlled device that provides delivery of solutions and fluids to the endoscope, endoscope channels, and accessories. Tergal 800 detergent and *Ortho*-Phthalaldehyde Solution high-level disinfectants (OPA) are utilized to provide high level disinfection of an endoscope and accessories.	Identical.

Process Parameters	• Standardized cycle parameters that cannot be altered by the operator. The critical process parameters monitored during processing:
	  • HLD contact time
	  • HLD temperature
	  • Water Volume
	  • HLD Volume
	  • Channel flow and pressure
		• Standardized cycle parameters that cannot be altered by the operator. The critical process parameters monitored during processing:
		  • HLD contact time
		  • HLD temperature
		  • Water Volume
		  • HLD Volume
		  • Channel flow and pressure
			Identical.

Process Monitors	• Flow Switches monitor fluid flow per channel • Sensors monitor fluid levels, drain completion • Pressure switch detects pressure output • Thermostatic switches monitor temperature of the HLD in the Reservoir and Processing Chamber • Software monitors Ultrasonics during Wash / Rinse Phase • Optical sensor that monitor fluid overfill	• Flow Switches monitor fluid flow per channel • Sensors monitor fluid levels, drain completion • Pressure switch detects pressure output • Thermostatic switches monitor temperature of the HLD in the Reservoir and Processing Chamber • Software monitors Ultrasonics during Wash / Rinse Phase • Optical sensor that monitor fluid overfill	Identical.
Design Features	• Intended for use with Tergal 800® Detergent and *Ortho*-Phthalaldehyde Solution high-level disinfectants (OPA) • Microprocessor controlled • Graphical User Interface that allows the operator to initiate and monitor device functions (Touch screen) • Processor Lid is opened with hands free operation • Devices with internal lumens are interfaced with the processing chamber using adapters • HLD is transfer from/to Reservoir – Processing Chamber • Device automatically rinses the load with 0.1µ filtered water after the Wash and HLD phases • Alcohol Injection / HEPA filtered air to aid in drying • Virtual Keyboard • Channel Monitoring LED (Internal Mount) • Electromechanical foot-activated switch processing chamber lid operation (Touch Pad)	• Intended for use with Tergal 800® Detergent and *Ortho*-Phthalaldehyde Solution high-level disinfectants (OPA) • Microprocessor controlled • Graphical User Interface that allows the operator to initiate and monitor device functions • Processor Lid is opened with hands free operation • Devices with internal lumens are interfaced with the processing chamber using adapters • HLD is transfer from/to Reservoir – Processing Chamber • Device automatically rinses the load with 0.1µ filtered water after the Wash and HLD phases • Alcohol Injection / HEPA filtered air to aid in drying • Keyboard • Channel Monitoring LED (External Mount) • Foot Pedal processing chamber lid operation	Similar. Subject device includes a Barcode Scanner and LED Process Status

Feature	Subject Wassenburg Medical, Inc. System 83 Revolve®	Predicate (K173590) Wassenburg Medical, Inc. System 83 Plus	Comparison
Design Features (Continued)	• Mounted Printer • Circuit Breaker (Relocated to Rear) • Front Door Switches • Chassis/Lids design change • Barcode Scanner utilized for data entry for users, patients, physicians, and instruments • LED Process Status Indicator	• Printer • Circuit Breaker • Front Door Switches • Hand Sprayer • Disinfectant Transfer	Similar. Subject device includes a Barcode Scanner and LED Process Status

The software verification and validation, EMC, electrical safety and cybersecurity testing performed (See Table 2) demonstrated that the software and electrical changes in the proposed device supports substantial equivalence to the predicate. The differences in technological characteristics between the subject System 83 Revolve and the predicate are minor and the testing demonstrates that the subject device performs comparably to the predicate device for the same intended use.

Feature	Subject Wassenburg Medical, Inc. System 83 Revolve®	Predicate (K173590) Wassenburg Medical, Inc. System 83 Plus	Comparison
Cycle Parameters			
HLD Contact Time	Minimum contact conditions of 12 minutes	Minimum contact conditions of 12 minutes	Identical.
HLD Contact Temperature	Minimum 20°C	Minimum 20°C	Identical.
Re-use Period	Not to exceed 14 days	Not to exceed 14 days	Identical.
HLD Reservoir Capacity	8 gallons	8 gallons	Identical.
Processing Chambers	Single Bay (Processing Chamber)	System 83 Plus 2	Identical.
Processing Chamber Capacity	6.5 gallons	6.5 gallons	Identical.
Maximum Endoscopes	2	2	Identical.
Ultrasonic Function	12 piezoelectric transducers operated at 40 kHz (±2)	12 piezoelectric transducers operated at 40 kHz (±2)	Identical.
Cycles	• Wash Only • Wash/Disinfect • Disinfect; three rinses	• Wash Only • Wash/Disinfect • Disinfect; three rinses	Identical.
Full Wash/Disinfect Cycle Process Parameters	Wash, One Rinse, Disinfect, Three Rinses, Alcohol and Air Purge	Wash, One Rinse, Disinfect, Three Rinses, Alcohol and Air Purge	Identical.
Wash	180 Seconds	180 Seconds	Identical.
Rinse	90 Seconds	90 Seconds	Identical.
Air	40 Seconds	40 Seconds	Identical.
Disinfect	720 Seconds	720 Seconds	Identical.
Rinse 1	60 Seconds	60 Seconds	Identical.
Rinse 2	60 Seconds	60 Seconds	Identical.
Rinse 3	90 Seconds	90 Seconds	Identical.
Air	40 Seconds	40 Seconds	Identical.
Alcohol and Air Purge	120 Seconds	120 Seconds	Identical.
Full Cycle Time	≈23 minutes[1]	≈23 minutes[1]	Identical.
Reprocessing Output / Method	Electronic record; Printout	Electronic record; Printout	Identical.

[1]Time does not include fill and drain time which can vary full cycle time.

Accessories			
Detergent	Tergal 800® detergent	Tergal 800® detergent	Identical.
High-Level Disinfectant (HLD)	*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%	*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%	Identical.
Scope Adapters	Adapters are required to connect to all lumens of the endoscope	Adapters are required to connect to all lumens of the endoscope	Identical.

Summary of Non-Clinical Testing
Shown in Table 2 is the new testing that was performed to evaluate the System 83 Revolve Washer/Disinfector.

Table 2. New Testing

Testing	Acceptance Criteria	Pass / Fail
Electrical Safety Conformance	Meets requirements per: • UL 61010-1:2012 Ed.3+R:06Jun2023 - Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements • CSA C22.2#61010-1:2012 Ed.3+U1;U2;A1;U3 - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 1: General Requirements • IEC 61010-2-040:2021 Ed.3 - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 2 - 040: Particular Requirements for Sterilizers and Washer-Disinfectors Used to Treat Medical Materials • CSA C22.2#61010-2-040:2021 Ed.3 - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 2 - 040: Particular Requirements for Sterilizers and Washer-Disinfectors Used to Treat Medical Materials	Pass
EMC Testing	• IEC 60601-1-2 ed 4.1 (2020-09) - Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests	Pass
Software Validation	Meets requirements per: • BS EN 62304, 2006+A1:2015 - Medical Device Software - software life cycle processes	Pass
Cybersecurity	Meets requirements per: • AAMI TIR57, 2016(R)2019 - Principles of medical device security - risk management	Pass

The subject device is the same device as the predicate with changes indicated in Table 1. The changes made to the subject device had no impact on the intended use of the subject device and no increased risk to reprocessing methods of the subject device. The following performance testing was performed for the predicate device and is used to support a determination of substantial equivalence.

Table 3. Testing performed for Predicate Device

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

Clinical Testing: Not applicable

Conclusion

The conclusions drawn from the testing demonstrates that the System 83 Revolve® Endoscope Washer/Disinfector is as safe, as effective, and performs as well as, or better than the legally marketed predicate device (K173590), Class II (21 CFR 876.1500), product code FEB.