October 29, 2026

Koehrer Medical Engineering GmbH
Colleen Boswell
Regulatory Consultant
Adolf-Flecken-Str. 10
North Rhine-Westphalia
Neuss, 41460
GERMANY

Re: K260356
Trade/Device Name: EndoColibri
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: Class I, reserved
Product Code: NYL
Dated: September 28, 2026
Received: September 28, 2026

Dear Colleen Boswell:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
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.	K260356

Please provide the device trade name(s).

EndoColibri

Please provide your Indications for Use below.

The EndoColibri is intended for the evacuation of endodontic irrigation solutions during root canal procedures.

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

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

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510(k) Summary

1. Submitter:

Koehrer Medical Engineering GmbH
Adolf-Flecken-Str. 10
North Rhine-Westphalia
Neuss, Germany 41460

Contact Person: Colleen Boswell
Telephone Number: +49 2131 151170

Date Prepared: September 24, 2026

2. Device:

Name of Device:	EndoColibri
Common Name:	Endodontic irrigation system used during root canal procedures
Classification Name:	Dental Handpiece and Accessories
Classification Regulation:	21 CFR 872.4200
Device Class:	I
Product Code:	NYL

3. Predicate Device:

Primary Predicate:	EndoVac Apical Negative Pressure Irrigation System, SybronEndo, K140685, Product Code NYL
Reference Device:	Multipiezo Pro, Multipiezo, Mectron S.p.A., K140965, Product Code ELC

4. Device Description

The **EndoColibri** is an irrigation system used in the field of endodontics for the final cleaning of an extirpated root canal system of a tooth. This system is comprised of 1) an ultrasonic handpiece adapter, 2) a suction tip composed of concentrically arranged polymer tubes - an outer MacroTube and an inner MicroTube embedded in a body component and 3) a suction hose with two adapters. The suction tip is attached via threading to the ultrasonic handpiece adapter using a torque wrench supplied by the manufacturer of the handpiece and the suction hose is attached to the top of the suction tip where it meets the handpiece adapter and is connected to either the dental office (chairside) high-volume evacuation system (HVE) or an external vacuum pump. A universal adapter is provided that connects the suction hose to the dental chairside unit via the hose's adapter which interfaces with the universal adapter. When the suction hose is connected to an external vacuum pump, the universal adapter is not required. A probe is provided to measure the distance from the coronal reference point to the root canal orifice. The distance from the coronal reference point to the root canal orifice is marked on the MacroTube. This marker guides accurate placement of the MacroTube so that it temporarily contacts the root canal wall at the canal

orifice, creating a temporary pressure change during irrigation. The MicroTube needs to be cut to a length that positions its tip 1-3 mm short of the established working length, measured from the marker on the MacroTube. This ensures that when the marker reaches the coronal reference point and the end of the MacroTube contacts the root canal wall at the canal orifice, the MicroTube tip is automatically positioned 1-3 mm short of working length for apical evacuation.

During use, ultrasonic vibration is transmitted through the adapter to the **EndoColibri** Tip. When the tip is advanced to the marked position on the outer MacroTube, the MacroTube temporarily contacts the root canal wall at the canal orifice. With suction active, this temporary contact produces pressure changes within the canal, while the inner MicroTube provides apical suction from a position 1-3 mm short of the established working length. Irrigants are delivered externally by the dental professional who is trained in the conventional method of irrigating the root canal using a syringe and needle during endodontic treatment. There is no integrated irrigation delivery system as part of the **EndoColibri**. The **EndoColibri** does not perform the delivery of the irrigating solution but instead, it facilitates evacuation of endodontic irrigation solutions during root canal procedures. The **EndoColibri** is used by licensed dental professionals.

5. Statement of Intended Use:

The **EndoColibri** is intended for the evacuation of endodontic irrigation solutions during root canal procedures.

6. Summary of Technological Characteristics with the Predicate Device

The technological characteristics of the subject **EndoColibri** are similar to the predicate device, EndoVac Apical Negative Pressure Irrigation System (K140685) and the reference device, Multipiezo Pro, Multipiezo (K140965) with the exception of 1) the addition of ultrasonic activation (predicate device) and 2) the absence of an integrated irrigation delivery system with the predicate and reference devices. There are no substantial technical or functional differences between the **EndoColibri** and the predicate and reference devices in terms of function and intended use. Both are endodontic irrigation systems (predicate device) used during root canal procedures and both use ultrasonic energy to generate mechanical micro-vibration of the tip to perform irrigation of the root canal (reference device) . See Table 1 below for technological characteristics and comparisons of the endodontic irrigation system used during root canal procedures.

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Table 1: Comparison of Subject, Predicate and Reference Devices

Element	EndoColibri (Proposed Device)	EndoVac Apical Negative Pressure Irrigation System (Primary Predicate Device PD)	Multipiezo (Reference Device RD)	Comparison
Manufacturer	Koehrer Medical Engineering GmbH	SybronEndo	Mectron SPA	N/A
510(k)	K260356	K140685	K140965	N/A
Target Users	Licensed Dental Professionals	Licensed Dental Professionals	Licensed Dental Professionals	Same
Common Name	Endodontic irrigation system used during root canal procedures	Endodontic irrigation system used during root canal procedures	Ultrasonic Scaler	Same as PD. Same as RD which indicates ultrasonic energy to generate micro-vibration of a tip to perform endodontic irrigation.
Indications For Use	The **EndoColibri** is intended for the evacuation of endodontic irrigation solutions during root canal procedures.	The EndoVac system is intended for the delivery and evacuation of endodontic irrigation solutions during root canal procedures.	The Multipiezo is a piezoelectric ultrasonic dental scaler intended for use, with the appropriate associated tip inserts, in the following dental applications: **Scaling:** All general procedures for removal of supragingival/	Similar to PD. The **EndoColibri** does not deliver irrigation fluid. Instead, clinicians perform the conventional procedure of irrigating a root canal by using standard syringes to apply solutions that are used in endodontic treatment. The PD evacuation is through a small microcannula so it incorporates an additional

Element	EndoColibri (Proposed Device)	EndoVac Apical Negative Pressure Irrigation System (Primary Predicate Device PD)	Multipiezo (Reference Device RD)	Comparison
			subgingival and interdental calculus/plaque deposits; **Periodontology:** Periodontal therapy and debridement for all types of periodontal diseases, including periodontal pocket irrigation and cleaning: **Endodontics:** All treatments for root canal reaming, irrigation, revision, filling, gutta-percha condensation and retrograde preparation; Restorative and **Prosthetics:** All general restorative procedures including cavity preparation, removal of prostheses, amalgam condensation,	coronal evacuation pathway while simultaneously delivering irrigant, providing a second pathway for removal of excess irrigant. The **EndoColibri** has a larger evacuation capacity that is designed in the coaxial tip. The specialized combined delivery/evacuation configuration used by the PD is not required for the **EndoColibri**. The difference is attributable to the **EndoColibri** tip architecture rather than to a difference in the fundamental irrigation principle. The coaxial microcannula/ macrocannula design provides sufficient evacuation capacity to maintain the intended fluid balance during operation without requiring an additional evacuation pathway at the irrigant-delivery site. A combined

Element	EndoColibri (Proposed Device)	EndoVac Apical Negative Pressure Irrigation System (Primary Predicate Device PD)	Multipiezo (Reference Device RD)	Comparison
			finishing of crown preparations, inlay/onlay condensation, and implants/restorations cleaning.	delivery/evacuation tip would not provide any functional benefit and does not alter the mechanism of action. Similar to RD. The **EndoColibri** uses ultrasonic energy from a standard EMS or Acteon/Satelec ultrasonic handpiece to generate micro-vibration of a tip to perform endodontic irrigation. This micro-vibration supports more effective cleaning but does not change the clinical purpose of the device. Ultrasonic vibration of irrigants is a widely accepted method in endodontic treatment. It enhances irrigant efficacy and improves debridement of the root canal system.
Method of Aspiration	Suction through tubing attached to the dental office (chairside) high-volume evacuation system (HVE) or an external vacuum pump	Suction through tubing attached to the dental office (chairside) high-volume evacuation system (HVE)	Use of a standard dental high-volume evacuation system (HVE)	Similar to PD and RD. More flexibility by allowing connection to either the chairside HVE or an external vacuum pump. This provides

Element	EndoColibri (Proposed Device)	EndoVac Apical Negative Pressure Irrigation System (Primary Predicate Device PD)	Multipiezo (Reference Device RD)	Comparison
				added versatility in clinical setups while maintaining the same core suction function as the PD and RD.
Suction Adapter	Universal Adapter with connection tubing: For HVE Connection tubing: For external vacuum pump	The Multi-Port Adapter critical to the functionality dimension in this component is the Outer Diameter (OD) due to compatibility with chairside HVE line. (OD = 0.434 in.)	N/A	Similar to PD. More adaptable by using a conical universal adapter that adjusts to different suction line diameters. The tapered outer diameter allows secure and functional connection to standard dental office HVE lines without requiring exact dimensional matching.
Mode of Operation	Manually Operated	Manually Operated	Electrically powered 100-240 VAC, 50/60 HZ	Same as PD. RD is electrically powered as is the standard EMS or Acteon/Satelec ultrasonic handpiece used with the **EndoColibri**.
Fluid Delivery System	N/A	Manual operation of the syringe plunger	One irrigating liquid bottle for ultrasonic scaling treatment	The **EndoColibri** does not feature an integrated delivery system like the PD and RD. Instead, clinicians perform the conventional procedure of irrigating a root canal by using standard

Element	EndoColibri (Proposed Device)	EndoVac Apical Negative Pressure Irrigation System (Primary Predicate Device PD)	Multipiezo (Reference Device RD)	Comparison
				syringes to apply solutions that are used in endodontic treatment. The PD has an additional coronal evacuation pathway while simultaneously delivering irrigant, providing a second pathway for removal of excess irrigant. The **EndoColibri** has a larger evacuation capacity that is designed in the coaxial tip. The specialized combined delivery/evacuation configuration used by the PD is not required for the **EndoColibri**. The difference is attributable to the **EndoColibri** tip architecture rather than to a difference in the fundamental irrigation principle. The coaxial microcannula/ macrocannula design provides sufficient evacuation capacity to maintain the intended fluid balance during operation

Element	EndoColibri (Proposed Device)	EndoVac Apical Negative Pressure Irrigation System (Primary Predicate Device PD)	Multipiezo (Reference Device RD)	Comparison
				without requiring an additional evacuation pathway at the irrigant-delivery site. A combined delivery/evacuation tip would not provide any functional benefit and does not alter the mechanism of action.
Single Use Disposable tips	Yes	Yes	No	Same as PD. RD has reusable tips.
MacroTube Dimensions	MacroTube: OD = 0.95±0.01mm or 0.90±0.01 mm	The MacroCannula critical to functionality dimension in this component is the OD due to the clinical application into the root canal cleaning procedure (OD = 0.020 ±0.001 in.)	N/A	Similar to PD - Slightly larger in outer diameter, while maintaining clinical suitability for root canal irrigation. The **EndoColibri** MacroTube has an OD of 0.90-0.95 mm, compared to predicate MacroCannula OD of 0.508 mm. Despite the size difference, the tube is designed to operate within the coronal portion of the canal and does not enter narrow apical regions, making the larger diameter clinically appropriate.

Element	EndoColibri (Proposed Device)	EndoVac Apical Negative Pressure Irrigation System (Primary Predicate Device PD)	Multipiezo (Reference Device RD)	Comparison
MacroCannula Material	Polypropylene (PP)	Titan Petchem SM598 (Ethylene Propylene Copolymer) / colorant (BLMT 2070)	N/A	Similar to PD - Made from polypropylene, a well-established biocompatible material in medical and dental applications, while the PD uses ethylene propylene copolymer. PP offers high chemical resistance, stability, and processability.
MicroCannula Dimensions	MicroTube: OD = 0.40±0.01 mm, 0.35±0.01mm or 0.55±0.01 mm	MicroCannula critical to functionality dimension in this component is the OD due to the clinical application into the root canal cleaning procedure (OD = 0.0125 to 0.0118 in.)	N/A	Similar to PD. Slightly larger in outer diameter, while remaining within clinically acceptable ranges for root canal irrigation. The **EndoColibri** MicroTube is available in three sizes: 0.35 ± 0.01 mm, 0.40 ± 0.01 mm and 0.55 ± 0.01 mm outer diameter, compared to approximately 0.30 -0.32 mm in the PD. This allows clinicians to select the appropriate tip size based on the anatomical conditions of the root canal.
MicroCannula Material	Polyetheretherketone (PEEK)	AISI 304 Stainless Steel	N/A	Similar to PD. Made from PEEK, a thermoplastic with

Element	EndoColibri (Proposed Device)	EndoVac Apical Negative Pressure Irrigation System (Primary Predicate Device PD)	Multipiezo (Reference Device RD)	Comparison
				established biocompatibility and clinical use in dental and medical devices, while the PD uses AISI 304 stainless steel. PEEK offers high strength, chemical resistance, and is commonly used in implantable and endodontic applications. Unlike metal, it is less brittle and less prone to microcrack propagation under cyclic loading. This is due to PEEK's low modulus of elasticity, which allows for controlled flexing under vibration.
MicroCannula Working Length	MicroTube working length 15 to 31 mm ±1mm	MicroCannula working length is from 14 to 30 mm ±0.5 mm	N/A	Similar to PD. A slight variation in the minimum and maximum range as well as tolerance. This difference is clinically insignificant. Both ranges fall within standard endodontic working lengths, and the function of the device remains unchanged. Therefore, the working

Element	EndoColibri (Proposed Device)	EndoVac Apical Negative Pressure Irrigation System (Primary Predicate Device PD)	Multipiezo (Reference Device RD)	Comparison
				length is considered substantially equivalent.
MicroCannula and MacroCannula	Negative pressure is used to clean the root canal with both the MicroTube & MacroTube. The working length is determined using the probe that measures the distance from the coronal reference point to the canal orifice. The MacroTube is marked accordingly, and the MicroTube is trimmed to be 1-3 mm short of the established working length.	Negative pressure is used to clean the root canal on both MicroCannula and MacroCannula. MacroCannula doesn't require any working length measurement but can be adjusted by clinician if needed. MicroCannula working length utilizes a sliding rubber stop as a reference point and can be used to set the working length. The rubber stop may move accidentally if pressure is applied to it.	N/A	Same as PD with respect to negative pressure cleaning using both MicroTube and MacroTube. However, the MicroTube working length is determined using an external measuring probe and adjusted by trimming the MicroTube to 1-3 mm short of the established working length. No mechanical stopper is used, ensuring precise apical positioning. This approach avoids potential errors associated with rubber stops, which may shift unintentionally if pressure is applied.
Vacuum Evacuation System	Single-use tip includes coaxial MacroTube and MicroTube	MicroCannula and MacroCannula are two independent single-use components	N/A	Similar to PD. **EndoColibri** uses a single-use coaxial tip combining MacroTube and MicroTube. This design achieves the same clinical effect, negative pressure irrigation and evacuation,

Element	EndoColibri (Proposed Device)	EndoVac Apical Negative Pressure Irrigation System (Primary Predicate Device PD)	Multipiezo (Reference Device RD)	Comparison
				with a simplified and compact component.
Vacuum Connection	Universal HVE adapter or external vacuum pump adapter	Multi-Port Adapter	Use of an aspirator from the HVE placed near the treatment area	Similar to PD. More versatile by offering a universal adapter compatible with both chairside HVE and external vacuum pumps. RD uses a traditional aspirator from the HVE.
Mechanism of Action	• Apical Negative Pressure • Ultrasonic Energy from compatible external source (EMS & Acteon/Satelec)	Apical Negative Pressure	Ultrasonic Energy	Same as PD and RD. **EndoColibri** does not generate its own ultrasonic energy. It uses a compatible external source - EMS & Acteon/Satelec ultrasonic system.
Ultrasonic Frequency Range	Acteon/Satelec - compatible: ≈ 27 kHz EMS - compatible: ≈ 28 kHz	N/A	24 - 36 kHz	Similar to RD. Both **EndoColibri** frequencies are within the 24-36 kHz working frequency of the RD.
Power Output	The **EndoColibri** does not contain an independent ultrasonic generator and does not generate its own power output. For ultrasonic operation, the following	N/A	Not specified in the available manufacturer documentation.	Similar to RD. Both the **EndoColibri** and the RD use controlled piezoelectric ultrasonic energy to generate mechanical vibration for endodontic

Element	EndoColibri (Proposed Device)	EndoVac Apical Negative Pressure Irrigation System (Primary Predicate Device PD)	Multipiezo (Reference Device RD)	Comparison
	compatible external source systems and clinical generator settings are specified: EMS compatible system - Woodpecker U600-LED: Proposed clinical setting 60% of the control scale. Manufacturer-stated generator output power range: 3-20 W. Satelec compatible system - Acteon Newtron Booster: Proposed clinical setting 75% of the control scale. Numerical ultrasonic output power in watts is not specified by the manufacturer.			irrigation. The **EndoColibri** is operated with established EMS and Satelec compatible ultrasonic systems at defined clinical settings of 60% and 75%, respectively. Frequency testing confirmed transmission of ultrasonic vibration to the **EndoColibri** Tip at approximately 28 kHz and 27 kHz, respectively. These frequencies are within the 24-36 kHz working frequency range specified for the RD. Because generator performance is reported using manufacturer-specific parameters, such as output wattage, electrical power consumption, or adjustable control levels, the stated values are considered together with the verified operating settings and the vibration measured directly at the **EndoColibri** Tip. This provides a device-specific

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Element	EndoColibri (Proposed Device)	EndoVac Apical Negative Pressure Irrigation System (Primary Predicate Device PD)	Multipiezo (Reference Device RD)	Comparison
				characterization of the mechanical vibration delivered at the working tip and supports comparison with the RD.

7. Performance Data

Biocompatibility Testing

The biocompatibility evaluation for the **EndoColibri** was conducted in accordance with ISO 10993-1 "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process" as recognized by FDA. The biocompatibility evaluation included the following tests:

1. Physical and/or chemical Information
2. Cytotoxicity
3. Sensitization
4. Irritation or intracutaneous reactivity
5. Material-mediated pyrogenicity
6. Acute systemic toxicity

The biocompatibility assessment conducted demonstrates adequate biocompatibility for the **EndoColibri**. Additionally, cytotoxicity testing was performed on direct and indirect patient-contacting components of the final, sterilized devices.

Sterilization Validation Testing

The sterilization validation testing for the **EndoColibri** was conducted in accordance with the partial cycle validation approach outlined in ANSI/AAMI/ISO 17665-1:2006/(R)2013, Annex D, the validation approach outlined in ANSI/AAMI/ISO 14937:2009/(R)2013, Annex D (Approach 3), and ISO 17665:2024.

The results validate each test article for the following sterilization parameters:

Pre-vacuum: 132°C (270°F) for 4 minutes with a 30-minute dry time

Cleaning Validation

The cleaning validation was performed for the **EndoColibri** in accordance with the 2015 FDA Guidance Document *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*, AAMI TIR12:2020, AAMI ST98:2022, and with ISO10993-5 Tests for In Vitro Cytotoxicity and the test method acceptance criteria were met.

Simulated Use Testing

The simulated use cycles were performed in accordance with AAMI ST98:2022 and the FDA guidance document *Reprocessing Medical Devices in Health Care Settings: Validation methods and labelling*. The testing was completed according to Koehrer Medical Engineering GmbH's recommended reprocessing procedures.

Bench Testing

1. Simulated Use Compatibility Testing - Adapter-to-Handpiece Fit, Retention and Connection
2. Simulated Use Functional Hydrodynamics Performance Test
3. Ultrasonic Frequency Performance Testing
4. Design and Development Verification Testing - Adapter Compatibility
5. Trimming Verification Testing

Clinical Studies

No human clinical testing was conducted to support substantial equivalence.

8. Conclusion as to Substantial Equivalence

The similarities in function, materials, performance testing and intended use of the **EndoColibri** with the legally marketed predicate device, EndoVac Apical Negative Pressure Irrigation System (K140685) and reference device, Multipiezo Pro, Multipiezo (K140965), support substantial equivalence.