May 15, 2023

Mectron S.p.A.
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K231391
Trade/Device Name: Combi Touch
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic scaler
Regulatory Class: Class II
Product Code: ELC, KOJ
Dated: May 12, 2023
Received: May 12, 2023

Dear Prithul Bom:

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,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231391

Device Name

combi touch

Indications for Use *(Describe)*

combi touch incorporates, within a single device, the functions of an ultrasonic scaler and of an air-polishing prophylaxis unit.

Ultrasonic scaler function:
combi touch, by using the appropriate associated inserts and the ultrasonic handpiece, is intended for use in the following dental applications:
• Removing supra and subgingival calculus deposits and stains from teeth
• Periodontal therapy and debridement for all types of periodontal disease, including periodontal pocket lavage with simultaneous ultrasonic tip movement
• Scaling and root planing
• Releasing crowns, bridges, inlays, and posts as well as condensing gutta percha
• Plugging for amalgam condensation
• Amalgam burnishing
• Preparing, cleaning and irrigating roots canals
• Cavity preparation
• Cleaning restorations and implant surfaces

Air-polishing prophylaxis function:
By using the appropriate air polishing handpiece, combi touch is intended for a complete supra-gingival and sub-gingival prophylaxis treatment.
The prophylaxis treatment is obtained by the projection of water, air and appropriate dental prophylaxis powders, onto the tooth surface. The device removes dental plaque, soft deposits, and surface stains from pits, grooves, interproximal spaces, or smooth surfaces of teeth.
combi touch is intended for the following oral prophylaxis procedures:
• Plaque removal for placement of sealants
• Surface preparation prior to bonding/cementation of inlays, onlays, crowns and veneers
• Surface preparation prior to placing composite restorations
• Effective plaque and stain removal for orthodontic patients
• Cleaning prior to bonding ortho brackets
• Cleaning implant fixtures prior to loading
• Stain removal for shade determination
• Plaque removal prior to fluoride treatment
• Plaque and stain removal prior to whitening procedures

combi touch is also intended for use as an air-polisher in patients suffering from periodontal disease.
combi touch is indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment.

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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electronic Submission Template And Resource (eSTAR)

Section: 510(k) Summary in accordance with 21 CRF 807.92

April 18, 2023

1. Administrative Information

Type of 510(k) submission: .....Premarket Notification

Device Common Name:.....Ultrasonic scaler/Air Polishing unit

Regulation description:.....Ultrasonic scaler

Proprietary names of the device: .....combi touch

Manufacturer: .....Mectron S.p.A.
Via Loreto, 15/a
Carasco - GE 16042, Italy

FDA Registration Number:.....3003933619

510(k) Owner: .....Mectron S.p.A.
Via Loreto, 15/a
Carasco - GE 16042, Italy

510(k) Preparer and Contact:.....Mr. Edoardo Tronchet
Regulatory Affairs Manager
Mectron S.p.A.

Telephone: +39 0185 35361
Cell: +39 3371605043
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2. Device identification:

Regulatory Class: .....Class II

Classification Regulation:....21 CFR 872.4850: Ultrasonic Scaler

Product Codes: .....Primary [ELC]
.....Secondary [KOJ]

Review Panel:.....Dental

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3. Identification of the Predicate / Reference Devices

Predicate device:

The Substantial Equivalence of the subject device is based on the predicate device.

Trade Name	Manufacturer	Product Code	510(k) Number
EMS AIR FLOW PROPHYLAXIS MASTER	EMS (Electro Medical System)	ELC, KOJ	K190124

Reference device:

For the Substantial Equivalence we have also considered the reference device:

Trade Name	Manufacturer	Product Code	510(k) Number
MULTIPIEZO	MECTRON Spa	ELC, EFB, EJR	K140965

4. Device description

The combi touch combines, in a single appliance, a multi-purpose piezoelectric scaler and water jet, air, and powder polisher, intended for complete supra- and subgingival dental prophylaxis.
In regards to the various possible ultrasonic treatments, combi touch can be used either connected directly to the main water supply in the dental practice, or with independent irrigation through the special liquid container, which can hold different types of medical solutions.
The appliance is equipped with an automatic tuning circuit which compensates the wear of the inserts, thus always allowing operation in conditions of maximum efficiency.
The operating principle of the polisher is based on the mechanical action obtained from a jet of various crystal types accelerated by a flow of compressed air. The kinetic energy thus imprinted at the particles, dissipates almost completely due to impact against the surface of the enamel, producing a gentle but effective cleaning action. The action is completed by a jet of water which, using the vacuum created around the air-polishing handpiece, has a bellshape around the main flow, thus producing a double effect: to prevent much of the rebound and the leakage of the cloud of powder and perform continuous washing of the treated area, dissolving the powder.

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5. Indications for use

combi touch incorporates, within a single device, the functions of an ultrasonic scaler and of an air-polishing prophylaxis unit.

Ultrasonic scaler function:

combi touch, by using the appropriate associated inserts and the ultrasonic handpiece, is intended for use in the following dental applications:

- Removing supra and subgingival calculus deposits and stains from teeth
- Periodontal therapy and debridement for all types of periodontal disease, including periodontal pocket lavage with simultaneous ultrasonic tip movement
- Scaling and root planing
- Releasing crowns, bridges, inlays, and posts as well as condensing gutta percha
- Plugging for amalgam condensation
- Amalgam burnishing
- Preparing, cleaning and irrigating roots canals
- Cavity preparation
- Cleaning restorations and implant surfaces

Air-polishing prophylaxis function:

By using the appropriate air polishing handpiece, combi touch is intended for a complete supra-gingival and sub-gingival prophylaxis treatment.
The prophylaxis treatment is obtained by the projection of water, air and appropriate dental prophylaxis powders, onto the tooth surface. The device removes dental plaque, soft deposits, and surface stains from pits, grooves, interproximal spaces, or smooth surfaces of teeth.
combi touch is intended for the following oral prophylaxis procedures:

- Plaque removal for placement of sealants
- Surface preparation prior to bonding/cementation of inlays, onlays, crowns and veneers
- Surface preparation prior to placing composite restorations
- Effective plaque and stain removal for orthodontic patients
- Cleaning prior to bonding ortho brackets
- Cleaning implant fixture prior to loading
- Stain removal for shade determination
- Plaque removal prior to fluoride treatment
- Plaque and stain removal prior to whitening procedure

The combi touch is also intended for use as an air-polisher in patients suffering from periodontal disease.

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The combi touch is indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment

6. Comparison of the proposed device and the predicate / reference devices

A comparison of the subject device with the predicate device is shown in the following Table 1.1.

	Table 1.1. Comparison Table for determination of Substantial Equivalence between combi touch device and Predicate / Reference Devices				
	Item for comparison	**COMBI TOUCH** **Subject Device**	**EMS AIRFLOW PROPHYLAXIS MASTER** **Primary Predicate Device - PD1 - K190124**	**MULTIPIEZO** **Reference Device - RD - K140965**	**Variations**
1	Manufacturer	MECTRON SPA Via Loreto 15/A 16042 Carasco - Italy	E.M.S. ELECTRO MEDICAL SYSTEMS S.A. 31 Ch. de la Vuarpilliere Nyon Vaud, SWITZERLAND CH-1260	MECTRON SPA Via Loreto 15/A 16042 Carasco - Italy	N/A
2	510(k) Number	Subject of this submission	K190124	K140965	N/A
3	Regulation panel	Dental	Dental	Dental	Identical to PD1 & RD
4	Regulation Number	21 CFR 872.4850	21 CFR 872.4850	21 CFR 872.4850	Identical to PD1 & RD
5	Common/Usual name and function	Ultrasonic scaler/Air Polishing unit	Ultrasonic scaler/Air Polishing unit	Ultrasonic scaler	Identical to PD1 Identical to RD for the ultrasonic scaler function
6	Product Code	Primary Product code: ELC Subsequent Product Code: KOJ	Primary Product code: ELC Subsequent Product Code: KOJ;	ELC	Identical to PD1 Identical to RD for code ELC
7	Classification	Class II	Class II	Class II	Identical to PD1 & RD
8	Combination Product	No	No	No	Identical to PD1 & RD
9	Device type	Table top device	Table top device	Table top device	Identical to PD1 & RD
10	Function	Ultrasonic scaling and Air-polishing	Ultrasonic scaling and Air-polishing	Ultrasonic scaling	Identical to PD1 and to RD for the ultrasonic scaler function

Table 1.1. Comparison Table for determination of Substantial Equivalence between combi touch device and Predicate / Reference Devices

	Item for comparison	COMBI TOUCH Subject Device	EMS AIRFLOW PROPHYLAXIS MASTER Primary Predicate Device - PD1 - K190124	MULTIPIEZO Reference Device - RD - K140965	Variations
11	Intended use	combi touch incorporates, within a single device, the functions of an ultrasonic scaler and of an air-polishing prophylaxis unit. Ultrasonic scaler function: combi touch, by using the appropriate associated inserts and the ultrasonic handpiece, is intended for use in the following dental applications: • Removing supra and subgingival calculus deposits and stains from teeth • Periodontal therapy and debridement for all types of periodontal disease, including periodontal pocket lavage with simultaneous ultrasonic tip movement • Scaling and root planing • Releasing crowns, bridges, inlays, and posts as well as condensing gutta percha • Plugging for amalgam condensation • Amalgam burnishing • Preparing, cleaning and irrigating roots canals • Cavity preparation • Cleaning restorations and implant surfaces Air-polishing prophylaxis function: By using the appropriate air polishing handpiece, combi touch is intended for a complete supra-gingival and sub-gingival prophylaxis treatment. The prophylaxis treatment is obtained by the projection of water, air and appropriate dental prophylaxis powders, onto the tooth surface. The device removes dental plaque, soft deposits, and surface stains from pits, grooves, interproximal spaces, or smooth surfaces of teeth. combi touch is intended for the following oral prophylaxis procedures: • Plaque removal for placement of sealants • Surface preparation prior to bonding/cementation of inlays, onlays, crowns and veneers • Surface preparation prior to placing composite restorations • Effective plaque and stain removal for orthodontic patients • Cleaning prior to bonding ortho brackets • Cleaning implant fixtures prior to loading • Stain removal for shade determination • Plaque removal prior to fluoride treatment • Plaque and stain removal prior to whitening procedures combi touch is also intended for use as an air-polisher in patients suffering from periodontal disease.	The AIRFLOW Prophylaxis Master combines the functions of an ultrasonic scaler and air-polishing unit within a single chassis. The AIRFLOW Prophylaxis Master is intended for use in the following dental and periodontal applications: •Removing supra and subgingival calculus deposits and stains from teeth •Periodontal pocket lavage with simultaneous ultrasonic tip movement •Scaling and root planning •Releasing crowns, bridges, inlays, and posts as well as condensing gutta percha •Plugging for amalgam condensation •Amalgam burnishing •Preparing, cleaning and irrigating roots canals •Cavity preparation •Cementing inlays and onlays •Retrograde preparation of roots canals The AIRFLOW Prophylaxis Master is intended for use in the cleaning and polishing of teeth by the projection of water, air, and dental powders onto the tooth surface. The device removes dental plaque, soft deposits, and surface stains from pits, grooves, interproximal spaces, or smooth surfaces of teeth. The AIRFLOW Prophylaxis Master can be used for the following cleaning procedures: •Plaque removal for placement of sealants •Surface preparation prior to bonding/cementation of inlays, onlays, crowns and veneers •Surface preparation prior to placing composite restorations •Effective plaque and stain removal for orthodontic patients •Cleaning prior to bonding ortho brackets •Cleaning implant fixture prior to loading •Stain removal for shade determination •Plaque removal prior to fluoride treatment •Plaque and stain removal prior to whitening procedure. The AIRFLOW Prophylaxis Masteris also intended for use as an air-polisher in patients suffering from periodontal disease. The AIRFLOW Prophylaxis Masteris indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment	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/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, finishing of crown preparations, inlay/onlay condensation, and implants/restorations cleaning.	Similar to PD1 except for “cementing inlays and onlays” due to the combi touch cannot perform it and previously cleared applications of RD

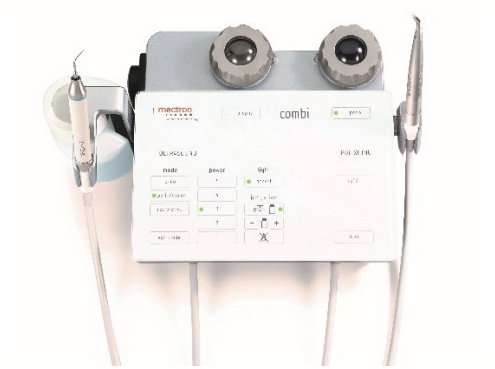
	Table 1.1. Comparison Table for determination of Substantial Equivalence between combi touch device and Predicate / Reference Devices				
	Item for comparison	**COMBI TOUCH** **Subject Device**	**EMS AIRFLOW PROPHYLAXIS MASTER** **Primary Predicate Device - PD1 - K190124**	**MULTIPIEZO** **Reference Device - RD - K140965**	**Variations**
		combi touch is indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment			
12	Anatomical site	Teeth and soft tissues in the mouth	Teeth and soft tissues in the mouth	Teeth and soft tissues in the mouth	Identical to PD1 & RD
13	Specific Treatment Site	Supragingival and Subgingival	Supragingival and Subgingival	Supragingival	Identical to PD1 Subgingival N/A for RD
14	Contact duration	Limited ≤ 24 hours	Limited ≤ 24 hours	Limited ≤ 24 hours	Identical to PD1 & RD
15	Materials in direct contact with patient:	Stainless steel Diamond coating Titanium nitride coating PEEK EVA+LPDE Viton PPSU TPX	Stainless steel Titanium COC PPSU EPDM PEEK Hytrel SC969	Stainless steel Diamond coating Titanium nitride coating PEEK	Similar to PD1 & RD. This difference doesn't impact on safety or clinical performance
16	Biocompatibility	Biocompatible	Biocompatible	Biocompatible	Similar to PD1 & RD
17	Main Components of the device	• Device core unit. • Irrigation tank complete with cap • Pedal FS-05 with cord and plug • Tank safety cap • Tank cap • Water supply hose with quick coupling • Air supply hose with quick coupling • Water filter • combi touch o-ring kit • Cleaning needle kit • SLIM Scaler Handpiece • Air-polishing handpiece 120° • Air-Polishing handpiece Perio • Water circuit disinfection kit	The Prophylaxis Master consists of: • Unit • Quick guide • Piezon® training tool • Reprocessing instructions • Wireless Foot pedal • US Power cable • AIR-FLOW® PLUS Prophylaxis Powder • AIR-FLOW® CLASSIC Prophylaxis Powder • AIR-FLOW® PLUS Powder chamber • AIR-FLOW® CLASSIC Powder chamber • Piezon® handpiece cord • AIR-FLOW® MAX handpiece cord • Box of AIR-FLOW® • Box of Piezon ® • Piezon® Bottle	• Control unit. • Irrigation liquid bottle • Foot-pedal with cord • Piezoelectric ultrasonic handpiece with led and cord. • Torque wrench to tighten the inserts on the handpiece. • Power supply cord. • Range of ultrasonic insert tips to be used according to the dental applications defined by the intended use. • Other accessories/attachments.	Similar There are minimal differences in the components related to the Ultrasonic scaler function and Air-polishing function

	Table 1.1. Comparison Table for determination of Substantial Equivalence between combi touch device and Predicate / Reference Devices				
	Item for comparison	**COMBI TOUCH** **Subject Device**	**EMS AIRFLOW PROPHYLAXIS MASTER** **Primary Predicate Device - PD1 - K190124**	**MULTIPIEZO** **Reference Device - RD - K140965**	**Variations**
		• Subgingival perio tips • K9 wrench • Ultrasonic Scaling insert S1-S • Ultrasonic Scaling insert P3 • Black power supply cable • Use and Maintenance Manual	• Water hose connector • Air hose connector • Clip + clean • Cleaner bottle		
18	Prophylaxis Powders used with the system	• Sodium Bicarbonate based powder • Glycine based powder	• PERIO (Glycine) • SOFT (Glycine) • CLASSIC (Sodium Bicarbonate) • PLUS (Erythritol)	N/A	The results of the tests indicated that combi touch, when used in combination with the commercially-available prophylaxis powders identified above: 1) was effective in the removal of simulated plaque from dental surfaces. 2) did not cause any damages to dental surfaces, as verified by the examination of tooth surfaces morphology after the treatment; 3) proved to be safe and effective for its intended use, producing erosion that is comparable to, or even lower than, the erosion produced by the predicate device.

	Table 1.1. Comparison Table for determination of Substantial Equivalence between combi touch device and Predicate / Reference Devices				
	Item for comparison	**COMBI TOUCH** **Subject Device**	**EMS AIRFLOW PROPHYLAXIS MASTER** **Primary Predicate Device - PD1 - K190124**	**MULTIPIEZO** **Reference Device - RD - K140965**	**Variations**
19	Prophylaxis powder tanks	Two separated and removable powder tanks, both housed in the casing of the device's console. One tank is dedicated to be used for the supra and subgingival treatments One tank is dedicated to be used for the subgingival treatments Both powder tanks are always available to be used according to the treatment selected from the end user on the console's touch panel.	Two removable powder tanks One tank is dedicated to be used for the supra and subgingival treatments One tank is dedicated to be used for the subgingival treatments The tanks can be used one at time only. The end-user must remove from the device's console the tank in use, (containing a type of powder) and insert the tank for the other type of powder)	N/A	Identical to PD1
20	Technological Characteristics (Mechanism of action)	**Ultrasonic Scaler Function:** Piezoelectric ultrasonic technology that generates mechanical micro-vibration of the insert tips. The piezoelectric transducer uses piezoceramic disks to convert the generator's electrical signal to ultrasonic vibration of the insert tip. **Air-polishing prophylaxis function:** It is based on the principle of projecting a pressurized air mixed with water and a prophylaxis powder on the treatment site (tooth surface).	**Ultrasonic Scaler Function:** Piezoelectric ultrasonic technology that generates mechanical micro-vibration of the insert tips. The piezoelectric transducer uses piezoceramic disks to convert the generator's electrical signal to ultrasonic vibration of the insert tip. **Air-polishing prophylaxis function:** It is based on the principle of projecting a pressurized air mixed with water and a prophylaxis powder on the tooth surface	**Ultrasonic Scaler Function**: Piezoelectric ultrasonic technology that generates mechanical micro-vibration of the insert tips. The piezoelectric transducer uses piezoceramic disks to convert the generator's electrical signal to ultrasonic vibration of the insert tip.	Similar to PD1 and to RD as regards the ultrasonic scaler function.
21	Ultrasonic Transducer Technological characteristics	Piezoelectric Ultrasonic Technology: The transducer uses piezoceramic disks to convert the generator's electrical signal to ultrasonic vibration of the scaler insert tip	Piezoelectric Ultrasonic Technology: The transducer uses piezoceramic disks to convert the generator's electrical signal to ultrasonic vibration of the scaler insert tip	Piezoelectric Ultrasonic Technology: The transducer uses piezoceramic disks to convert the generator's electrical signal to ultrasonic vibration of the scaler insert tip	Identical to PD1 & RD
22	Led system incorporated inside the ultrasonic scaler handpiece to provide illumina-tion of the operative site.	YES	YES	YES	Similar to PD1. Identical to RD
23	Handpieces	The subject device can be used with five separate handpieces:	The predicate device can be used has three separated handpieces. - One ultrasonic piezoelectric handpiece intended for the scaling treatments.	The device operates with one piezoelectric ultrasonic handpiece.	Similar to PD1 for scaling and prophylaxis treatment Identical to RD for the ultrasonic scaler function

	Table 1.1. Comparison Table for determination of Substantial Equivalence between combi touch device and Predicate / Reference Devices				
	Item for comparison	**COMBI TOUCH** **Subject Device**	**EMS AIRFLOW PROPHYLAXIS MASTER** **Primary Predicate Device - PD1 - K190124**	**MULTIPIEZO** **Reference Device - RD - K140965**	**Variations**
		- Two ultrasonic piezoelectric handpiece intended for the scaling treatments (SLIM scaler handpiece and LED scaler handpiece) - One air-polishing handpiece 120° dedicated to perform supra-gingival prophylaxis treatment. - One air-polishing handpiece 90° dedicated to perform supra-gingival prophylaxis treatment. - One air-polishing handpiece PERIO dedicated to perform sub-gingival use in periodontal treatments – use in conjunction with the subgingival perio tips	- One air-polisher handpiece dedicated to perform supra-gingival prophylaxis treatment. - One air-polisher handpiece dedicated to perform sub-gingival prophylaxis treatment.		
24	Subgingival periodontal tip	YES	YES	N/A	Similar to PD1
25	Max power Consumption	90 VA	700 VA	90 VA	This difference doesn't impact on safety or clinical performance. Identical to RD
26	Ultrasound Frequency	24 kHz to~36 kHz	24 kHz to~32 kHz	24 kHz to~36 kHz	Similar to PD1 and identical to RD
27	Flow rate adjustment	Mechanical regulator + Touch panel	Mechanical regulator	Touch panel	Similar to PD1 and identical to RD
28	Foot pedal	Wired	Wireless or wired	Wired	Similar to PD1 and identical to RD
29	Electrical power input	100 - 240 VAC - 50/60 Hz.	100 - 240 VAC - 50/60 Hz.	100 - 240 VAC - 50/60 Hz.	Identical to PD1 & RD
30	Water delivery system	One irrigating liquid bottle for ultrasonic scaling treatment Connection to external water supply for both ultrasonic scaling and air-polishing treatment	One irrigating liquid bottle for ultrasonic scaling treatment Connection to external water supply for both ultrasonic scaling and air-polishing treatment	One irrigating liquid bottle for ultrasonic scaling treatment	Identical to PD1 and RD for the scaling treatment

	Table 1.1. Comparison Table for determination of Substantial Equivalence between combi touch device and Predicate / Reference Devices				
	Item for comparison	**COMBI TOUCH** **Subject Device**	**EMS AIRFLOW PROPHYLAXIS MASTER** **Primary Predicate Device - PD1 - K190124**	**MULTIPIEZO** **Reference Device - RD - K140965**	**Variations**
31	Electrical safety	Complies with IEC 60601-1	Complies with IEC 60601-1	Complies with IEC 60601-1	Identical to PD1 & RD
32	Electromagnetic Compatibility	Complies with IEC 60601-1-2	Complies with IEC 60601-1-2	Complies with IEC 60601-1-2	Identical to PD1 & RD
33	Device contains software?	YES	YES	YES	Identical to PD1 & RD
34	Parts supplied sterile	YES (Subgingival Perio Tips). The shelf life is 5 years	NO	N/A	The Subgingival Perio Tip material composition was found to be incompatible with reprocessing by steam sterilization due to a melting point lower than the required sterilization temperature (132°C). Also for the US market, it was decided to make the Subgingival Perio Tip available in sterile condition and for single use only.
35	Parts need to be sterilized prior use?	• YES • SLIM scaler handpiece and LED scaler handpiece • air-polishing handpiece 120° • air-polishing handpiece 90° • air-polishing handpiece PERIO • Ultrasonic Scaling Inserts • Torque wrenches • Irrigation kit	• YES • AIR-FLOW® handpiece • PERIOFLOW® handpiece • Piezon ® handpiece • Scaler Insert • Torque wrench • CLIP + CLEAN	YES • SLIM scaler handpiece and LED scaler handpiece • Ultrasonic Scaling Insets • Torque wrenches	Similar to PD1 and RD
36	Shelf life	Unrestricted	Unrestricted	Unrestricted	Identical
37	Recommended sterilization method	Autoclaving (Steam Sterilization)	Autoclaving (Steam Sterilization)	Autoclaving (Steam Sterilization)	Identical to PD1 & RD

	Table 1.1. Comparison Table for determination of Substantial Equivalence between combi touch device and Predicate / Reference Devices				
	Item for comparison	**COMBI TOUCH** **Subject Device**	**EMS AIRFLOW PROPHYLAXIS MASTER** **Primary Predicate Device - PD1 - K190124**	**MULTIPIEZO** **Reference Device - RD - K140965**	**Variations**
38	Flush function: washing of the liquid circuit	YES	YES	YES	Similar to PD1 and identical to RD
39	Compressed air supply	4 to 8 Bar	4.5 to 7 Bar	N/A	Similar-Difference with no impact on the safety and effectiveness of the subject device
40	Water supply	1 to 6 Bar	2 to 5 Bar	N/A	Similar -Difference with no impact on the safety and effectiveness of the subject device
41	Dimensions: (HxWxD) Weight (approx)	145 x 260 x 410 4,8 Kg 	245 x 260 x 290 5 Kg max. 	145 x 230 x 320 2,4 Kg 	Similar to PD1 and RD since all the devices have dimensions and weights consistent with the table top use

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Substantial Equivalence Discussion

The proposed device and the predicate device AIRFLOW Prophylaxis Master (K190124 cleared on 20/10/2019) have the intended use substantially identical

The proposed device and the predicate device share also many identical features, including identical/equivalent principle of operation and technological characteristics

The differences identified in the above table 1.1 clearly have no impact on safety or effectiveness of the device. Any differences identified in above table does not introduce any new questions regarding safety and effectiveness.
These considerations are also confirmed by the performance test carried out in comparison with the predicate device PD1.

The data presented in this submission demonstrates the identities existing between the combi touch device and the predicate devices, and thus support a finding of substantial equivalence between the subject device and the referenced predicated devices, which are already in commercial distribution in the United States.

7. Summary of Non-Clinical Testing – List of Standards

Testing was performed to verify compliance of the combi touch with the list standards listed here below:

Standard	Title	FDA Recognition Number
CEI UNI EN ISO 14971:2019	Medical devices - Application of risk management to medical devices	5-125
ISO/TR 24971:2020	Medical devices — Guidance on the application of ISO14971	-
IEC 60601-1:2015, AMD1:2012	Medical electrical equipment — Part 1 — General Requirements for Safety	19-46
IEC 60601-1-2:2014; IEC 60601-1-2:2014/AMD1:2020	Medical Electrical equipment - PART 1-2: General Requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Disturbances — Requirements and tests	19-36
IEC 60601-1-6:2010 AMD1:2013	General requirements for basic safety and essential performance - Collateral standard: Usability	5-89
IEC 62366: 2007/AMD1:2014	Medical devices - Application of usability engineering to medical devices	-
IEC 62304:2006 + IEC 62304:2006/AMD1:2015	Medical device software - Software life-cycle processes	13-79
ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems	14-499
ISO 7153-1:2016	Surgical Instruments – Materials – Part 1: Metals	8-344
ASTM F899-20	Standard Specification for Wrought Stainless Steel for Surgical Instruments	8-527
ASTM F136-13	Standard Specification for Wrought Titanium-6Aluminum- 2013 4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)	8-377
EN 10088-3:2014	Stainless steels - Part 3: Technical delivery conditions for semi-finished products, bars, rods, wire, sections and bright products of corrosion resisting steels for general purposes	-
EN ISO 11737-1:2018/AMD 1:2021	Determination of a population of microorganisms on products	14-577
EN ISO 11737-2:2020	Tests of sterility performed in the definition, validation and maintenance of a sterilization process	14-540

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Standard	Title	FDA Recognition Number
EN 62353:2015	Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment	-
IEC 62471:2006 EN 62471:2008	Photo biological safety of lamps and lamp systems	12-249
IEC 80601-2-60:2019	Medical electrical equipment – Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment	4-262
ISO 10993-1:2018	Biological evaluation of medical devices – Evaluation and testing within a risk management process	2-258
UNI EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	2-245
UNI EN ISO 10993-7:2008	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009), AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)]	2-275
ISO 10993-10:2021	Biological evaluation of medical devices — Part 10: Tests skin sensitization	2-296
ISO 10933-11:2017	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity	2-255
ISO 10993-12:2021	Biological evaluation of medical devices Sample preparation and reference materials	2-289
ISO 11607-1:2019	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems	14-530
ISO 11607-2:2019	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes	14-530
UNI EN 1422:2014	Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods	-
EN ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	5-134
UNI 556-1:2002/AC:2006	Sterilization of Medical devices – Requirements for medical devices to be designated “STERILE” – Part 1 – Requirements for terminally sterilized medical devices.	-
AAMI ST77:2013/®:2018	Containment devices for reusable medical device sterilization.	14-396
AAMI ST79:2017	Comprehensive guide to steam sterilization and sterility assurance in health care facilities.	14-562
AAMI ST8:2013	Hospital Steam Sterilizers	14-406
ISO 15883-1:2007	Washer-disinfectors – Part 1: General requirements, terms and definitions and tests	-
ISO/TS 15883-5:2005	Washer-disinfectors — Part 5: Test soils and methods for demonstrating cleaning efficacy 2005.	-
ISO 15883-5:2021	Washer-disinfectors – Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy	-
AAMI TIR12:2010	Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers	-
AAMI TIR28:2016	Product adoption and process equivalence for ethylene oxide sterilization	-
AAMI TIR30:2011 (R2016)	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices	-
ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices	14-578
EN ISO 15883-4:2018	Washer-disinfectors – Part 4: Requirements and tests for washer disinfectors employing chemical disinfection for thermolabile endoscopes	-
ASTM E1837− 96 (Reapproved 2014)	Standard Test Method to Determine Efficacy of Disinfection Processes for Reusable Medical Devices (Simulated Use Test)	-
AFNOR NF T 72-281, 2014	Methods of airborne disinfection of surfaces Determination of bactericidal, yeasticidal, mycobactericidal, tuberculicidal, sporicidal and virucidal activity, including bacteriophages.	-
EN 1276:2019	Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and	-

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Standard	Title	FDA Recognition Number
	antiseptics used in food, industrial, domestic and institutional areas – Test method and requirements (phase 2, step 1).	
EN ISO 11135:2014/A1:2019	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	14-529
ISO 11138-1:2017	Sterilization of health care products — Biological indicators — Part 1: General requirements	14-502
ISO 11138-2:2017	Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes	-
ISO 11138-3:2017	Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes	-
ISO 11138-7:2017	Sterilization of health care products — Biological indicators — Part 7: Guidance for the selection, use and interpretation of results	-
EN ISO 11737-1:2015	Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganism on products	-
EN ISO 11737-2:2020	Sterilization of health care products – Microbiological methods – Part 2: Test of sterility performed in the definition, validation and maintenance of a sterilization process	-
UNI EN 868-2:2009	Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods	-
ISO 17665-1:2006	Sterilization of health care products — Moist heat — Requirements for development, validation and routine control of a sterilization process for medical devices.	14-333
AAMI/ISO TIR 17665-2:2009	Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ISO 17665-1.	14-277
EN ISO 5349-1:2001	Mechanical vibration - Measurement and evaluation of human exposure to hand-transmitted vibration - Part 1: General requirements	-
ISTA 2A :2011	Packaged-Products 150 lb (68 kg) or less	-
UNI EN ISO 5349-2:2015	Mechanical vibration — Measurement and evaluation of human exposure to hand-transmitted vibration — Part 2: Practical guidance for measurement at the workplace	-
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer	5-135

The results of the tests have demonstrated the safety and effectiveness of the Combi Touch device for the indication for use reported in section 5.

8. Summary of Clinical Testing

Animal or clinical testing were not required to prove combi touch's substantial equivalence when compared to the predicate/reference devices

9. CONCLUSION

Based on the comparative analysis and testing contained within this submission, it is concluded that the combi touch device has intended use, safety and effectiveness profile, and technological characteristics, substantially equivalent to the identified predicate / reference devices which are already in commercial distribution in the United States.