January 28, 2026

E.M.S. Electro Medical Systems S.A.
℅ Sheila Hemeon-Heyer
President
Heyer Regulatory Solutions
125 Cherry Lane
Amherst, Massachusetts 01002

Re: K253254
Trade/Device Name: GBT Machine Airflow Prophylaxis Master
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: Class II
Product Code: ELC, KOJ
Dated: September 29, 2025
Received: September 29, 2025

Dear Sheila Hemeon-Heyer:

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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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OHT1: Office of Ophthalmic, Anesthesia,
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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.	K253254

Please provide the device trade name(s).

GBT Machine Airflow Prophylaxis Master

Please provide your Indications for Use below.

The GBT Machine AIRFLOW Prophylaxis Master combines the functions of an ultrasonic scaler and air-polishing unit within a single chassis.

The GBT Machine 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 planing

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

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

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

510(k) #: K253254

510(k) Summary

Prepared on: 2026-01-14

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	E.M.S. Electro Medical Systems S.A.
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Correspondent Contact	Ms. Sheila Hemeon-Heyer
Correspondent Contact Email	Sheila@Heyer-Regulatory.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	GBT Machine Airflow Prophylaxis Master
Common Name	Ultrasonic scaler
Classification Name	Scaler, Ultrasonic
Regulation Number	872.4850
Product Code(s)	ELC, KOJ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K190124	AIRFLOW Prophylaxis Master	ELC, KOJ

Device Description Summary

21 CFR 807.92(a)(4)

The GBT Machine AIRFLOW® Prophylaxis Master is a dental device that combines ultrasonic scaling and air-polishing functions into a single integrated system. It is a modified version of the AIRFLOW Prophylaxis Master previously cleared under 510(k) K190124. The device is compatible with EMS ultrasonic scaling instruments cleared under 510(k) K190124 and with prophylaxis powders including AIR-FLOW CLASSIC (K190124), AIR-FLOW PERIO (K190124), and AIR-FLOW PLUS (K171189).

The device is composed of a central control unit, interchangeable handpieces (PIEZON, AIRFLOW, and PERIOFLOW), powder chambers, an irrigation system, and a wireless Bluetooth foot pedal. The control unit contains the power supply, ultrasonic generator, powder and fluid delivery circuits, and a microprocessor control system.

Treatment is activated via the wireless foot pedal, and the control panel allows the clinician to adjust power and irrigation levels. The ultrasonic scaling function operates in the 24–32kHz range using piezoelectric vibration to remove calculus and stains, while the air-

polishing function sprays a mixture of air, water, and powder for supragingival and subgingival cleaning.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The GBT Machine AIRFLOW Prophylaxis Master combines the functions of an ultrasonic scaler and air-polishing unit within a single chassis.

The GBT Machine 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 planing

The GBT Machine 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.

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

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device has a subset of the indications for use for the periodontal applications and the same indications for use for the cleaning applications as compared to those cleared for the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The GBT Machine AIRFLOW® Prophylaxis Master shares the same fundamental technological characteristics as the predicate device, the AIRFLOW® Prophylaxis Master (K190124). Both devices integrate ultrasonic scaling and air-polishing functions within a single control unit. The scaling function operates on the basis of piezoelectric technology, while the air-polishing function projects a controlled mixture of air, water, and powder to remove plaque and stains.

Several technological improvements have been introduced in the GBT Machine to enhance usability, connectivity, and ergonomics. These include:

- An updated ultrasonic generator module with improved performance but same frequency range and power
- Electronic water flow control replacing the mechanical flow regulator
- Improved water bottle irrigation system
- New cart design
- Simplified user settings providing the same power/pressure to promote consistent use
- Default GBT setting providing optimum power and water flow settings for the majority of treatments
- RFID-based handpiece recognition to preconfigure settings automatically.
- Wi-Fi and LTE connectivity, enabling secure data transmission for usage monitoring, remote diagnostics, and software updates.

These connectivity features (Wi-Fi, LTE, RFID) do not impact the treatment functionality or the indications for use of the device. No new safety or effectiveness concerns are introduced by these additions. The device intended use, indications for use, principles of operation, anatomical sites, patient-contacting materials, and key performance characteristics remain unchanged.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Design verification and validation activities were performed on the GBT Machine AIRFLOW Prophylaxis Master to ensure conformity with applicable requirements and to demonstrate substantial equivalence to the predicate device. These activities included:

- Electrical safety testing to IEC 60601-1:2005 + A1:2012 + A2:2020 (Edition 3.2) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance and IEC 80601-2-60:2019 Medical electrical equipment Part 2: Particular requirements for basic safety and essential performance of dental equipment
- Electromagnetic compatibility (EMC) testing to 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
- Wireless communication coexistence and testing to IEEE/ANSI C63.27-2021 American National Standard for Evaluation of Wireless Coexistence
- Cybersecurity testing (Static Analyses and Penetration Testing)
- Performance testing according to ISO 18397:2016 Dentistry Powered scalers, ISO 7494-1:2018 Dentistry Part 1: General requirements and test methods, and ISO 7494-2:2022 Dentistry Part 2: Water and air supply
- Bench testing to internal company protocols to verify the implementation of the changes introduced since the predicate device resulting in the GBT Machine Airflow Prophylaxis Master
- Software testing to verify correct operation of the five discrete software systems in the device

No clinical tests were submitted, referenced, or relied on in this 510(k) for a determination of substantial equivalence.

The design modifications introduced in the GBT Machine AIRFLOW Prophylaxis Master were specifically evaluated to ensure they do not negatively impact device performance, reliability, or safety. These modifications do not alter the intended use or raise new questions of safety or effectiveness compared to the predicate device. User instructions and labeling have been updated accordingly to reflect these changes.