September 28, 2022

Guilin Woodpecker Medical Instrument Co., Ltd.
% Charles Mack
Principal Engineer
IRC
2950 E Lindrick Drive
Chandler, Arizona 85249

Re: K221548
Trade/Device Name: Dental Air Polishing Handpiece
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EFB
Dated: August 31, 2022
Received: August 31, 2022

Dear Charles Mack:

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, 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.

510(k) Number *(if known)*

K221548

Device Name
Dental Air Polishing Handpiece

Indications for Use *(Describe)*

The Dental Air Polishing Handpiece, AP-H Plus is a dental handpiece intended for use in the cleaning and polishing of teeth by the projection of a mixture of water, air, and powder onto the tooth surface. The device removes soft deposits and areas of discoloration and can be used to prepare teeth for dental procedures such as the placement of composite fillings, porcelain inlays, and laminate veneers. The device can be used to clean implant abutments and to clean teeth prior to treatments such as shade matching, fluoridation, and bleaching. The device can also be used to degrease crowns and bridges prior to placement and clean fixed bands and brackets on orthodontic appliances.

The Dental Air Polishing Handpiece, AP-H Plus is intended for patients suffering from periodontal disease.

The Dental Air Polishing Handpiece, AP-H Plus is indicated for the non-surgical removal of subgingival plaque in pockets up to 4 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.

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

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

K221548 510(k) SUMMARY

Preparation Date:	September 27, 2022
Manufacturer's Name and Address:	Guilin Woodpecker Medical Instrument Co., Ltd Information Industrial Park, Guilin National High-Tech Zone, Guilin City, Guangxi Province, China 541004
Corresponding Official:	Charles Mack
Telephone Number:	931-625-4938
Email Address:	charliemack@irc-us.com
Trade Name:	Dental Air Polishing Handpiece AP-H Plus
Common Name(s):	handpiece, air-powered, dental
Regulation Name(s):	Dental handpiece and accessories.
Regulation Number(s):	21CFR872.4200
Product Code:	EFB
Device Class:	Class II
Predicate Device:	E.M.S. Electro Medical Systems S.A. K151912

Device Description:

The Dental Air Polishing Handpiece, AP-H Plus is an air driven dental handpiece for the use by a trained professional in the field of supragingival and the subgingival treatment. The devices are air-powered handpieces that are reusable.

The proposed Dental Air Polishing Handpiece, AP-H Plus device is similar in design to the predicates AIR-FLOW handy 3.0 PLUS (K151912) . The proposed Dental Air Polishing Handpiece, AP-H Plus device and the predicates connect to a standard air turbine connection on a dental operative unit and deliver a mixture of water, air, and prophylaxis powder to a treatment site. The subject Dental Air Polishing Handpiece is comprised of a supragingival handpiece (model: AP - 1 Plus) a subgingival handpiece (model: AP - 2 Plus), spray head, nozzle, powder storage chamber, and tail cord connector.

Indications for Use

The Dental Air Polishing Handpiece, AP-H Plus is a dental handpiece intended for use in the cleaning and polishing of teeth by the projection of a mixture of water, air, and powder onto the tooth surface. The device removes soft deposits and areas of discoloration and can be used to prepare teeth for dental procedures such as the placement of composite fillings, porcelain inlays, and laminate veneers. The device can be used to clean implant abutments and to clean teeth prior to treatments such as shade matching, fluoridation, and bleaching. The device can also be used to degrease crowns and bridges prior to placement and clean fixed bands and brackets on orthodontic appliances.

The Dental Air Polishing Handpiece, AP-H Plus is intended for patients suffering from periodontal disease.

The Dental Air Polishing Handpiece, AP-H Plus is indicated for the non-surgical removal of subgingival plaque in pockets up to 4 mm after initial periodontal treatment.

Comparison of Technological Characteristics with the Predicate Device

Characteristics	Subject Device	Predicate Device	Discussion
Device	Dental Air Polishing Handpiece, AP-H Plus	AIR-FLOW handy 3.0 PLUS	-
510K Applicant	Guilin Woodpecker Medical Instrument Co., Ltd.	E.M.S. ELECTRO MEDICAL SYSTEMS S.A.	-
510(K) Number	Pending	K151912	-
Regulation Number	CFR872.4200	CFR872.4200	Identical
Product Code	EFB	EFB	Identical
Classification Name	Air-powered dental handpiece	Air-powered dental handpiece	Identical
OTC or Prescription	Prescription Use	Prescription Use	Identical
Medical Specialty	Dental	Dental	Identical

Characteristics	Subject Device	Predicate Device	Discussion
Indication for Use	The Dental Air Polishing Handpiece, AP-H Plus is a dental handpiece intended for use in the cleaning and polishing of teeth by the projection of a mixture of water, air, and powder onto the tooth surface. The device removes soft deposits and areas of discoloration and can be used to prepare teeth for dental procedures such as the placement of composite fillings, porcelain inlays, and laminate veneers. The device can be used to clean implant abutments and to clean teeth prior to treatments such as shade matching, fluoridation, and bleaching. The device can also be used to degrease crowns and bridges prior to placement and clean fixed bands and brackets on orthodontic appliances. The Dental Air Polishing Handpiece, AP-H Plus is intended for patients suffering from periodontal disease. The Dental Air Polishing Handpiece, AP-H Plus is indicated for the non-surgical removal of subgingival plaque in pockets up to 4 mm after initial periodontal treatment.	The AIR-FLOW handy 3.0 PLUS is a dental handpiece intended for use in the cleaning and polishing of teeth by the projection of a mixture of water, air, and EMS prophylaxis powder onto the tooth surface. The device removes soft deposits and areas of discoloration and can be used to prepare teeth for dental procedures such as the placement of composite fillings, porcelain inlays, and laminate veneers. The device can be used to clean implant abutments and to clean teeth prior to treatments such as shade matching, fluoridation, and bleaching. The device can also be used to degrease crowns and bridges prior to placement and clean fixed bands and brackets on orthodontic appliances. The AIR-FLOW handy 3.0 PLUS is intended for patients suffering from periodontal disease. The AIR-FLOW handy 3.0 PLUS is indicated for the non-surgical removal of subgingival plaque in pockets up to 4 mm after initial periodontal treatment.	Identical

Characteristics	Subject Device	Predicate Device	Discussion
Treatment Site	Supragingival and Subgingival	Supragingival and Subgingival	Identical
Compatible Prophylaxis Powders	Glycine Sodium bicarbonate Erythritol	Glycine	The subject device including two additional compatible prophylaxis powders; They confirm to the same performance requirement as predicate device
Function	Air-polishing	Air-polishing	Identical
Mechanism of Action	Projection of water/air/powder mixture	Projection of water/air/powder mixture	Identical
Operation Mode	Continuous operation	Continuous operation	Identical
Service Pressure to the Turbine Connection	Water: 1 to 2.2 bar (1000-2200 hPa) Air: Static pressure 2.7 to 3.5 bar (2700-3500 hPa)	Water: 1 to 2.2 bar (1000-2200 hPa) Air: Static pressure 2.7 to 3.5 bar (2700-3500 hPa)	Identical
Operating Conditions	+10°C to +40°C, 30% to 75% relative humidity, 700 hPa to 1060 hPa air pressure,	+10°C to +40°C, 30% to 75% relative humidity, 700 hPa to 1060 hPa air pressure,	Identical
Usage	Re-useable	Re-useable	Identical
Weight	Approx. 0.125kg	Approx. 0.150kg	Similar
How Supplied	Non-sterile; Subject to be sterilized before each use	Non-sterile; Subject to be sterilized before each use	Identical
Applicable Sterilization	Moist heat - Autoclave sterilization	Moist heat - Autoclave sterilization	Identical
Performance	ANSI/AAMI ST79 ANSI/AAMI/ISO 17665-1 IEC 62366 ISO 15223-1 ISO 17664	ANSI/AAMI ST79 ANSI/AAMI/ISO 17665-1 IEC 62366 ISO 15223-1 ISO 17664	Identical
Biocompatibility	Complies with ISO 10993-1	Complies with ISO 10993-1	Identical

Performance Testing

Performance testing was provided in support of the substantial equivalence determination and to validate and verify that the Dental Air Polishing Handpiece, AP-H Plus met all requirements of related international standards. The results of these tests demonstrate compliance with the requirements of the consensus standards noted below.

Non-clinical Testing

Performance Testing

- ISO 20608 First edition 2018-04 Dentistry - Powder jet handpieces and powders
- ISO 9168 Dentistry - Hose connectors for air driven dental handpieces

Biocompatibility Information

The subject device is classified as surface device and contact mucosal membrane for limited contact (duration ≤ 24 h). The following tests were performed to ensure compliance with biocompatibility requirements.

- ISO10993-1: BIOLOGICAL EVALUATION OF MEDICAL DEVICES
- ISO10993-5 Cytotoxicity Tests
- ISO10993-10 Skin Irritation test
- ISO10993-10 Oral Mucosa Irritation test
- ISO10993-10 Sensitization Test

Sterility Information

The handpiece is supplied non-sterile and subject to be sterilized by autoclave prior to use. Fractional pre-vacuum cycle at 132°C for 4 min and a drying time of 20 min same as predicate device.

Recommended sterilization method which has been validated as below:

Sterilization validation for the handpieces was performed in accordance with the standards noted below:

- ANSI AAMI ST79:2017, Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- ISO 17665-1:2006, Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices (Sterility)

The cleaning method has been validated for the handpiece and the powder chamber per AAMI TIR30 and the FDA Guidance Reprocessing Medical Devices in Health

Care Settings: Validation Methods and Labeling.

The intermediate-level disinfection method has been validation for the powder chamber and cord per AAMI TIR12:

Clinical Test:

No clinical study is included in this submission.

Shelf Life:

The device is not delivered sterile and low likelihood of time-dependent product degradation, therefore, the shelf-life is not applicable.

Conclusions:

The differences between the predicate and the subject device do not raise any new or different questions of substantial equivalence. The Dental Air Polishing Handpiece, AP-H Plus is substantially equivalent to the E.M.S. Electro Medical Systems S.A., Inc. AIR-FLOW handy 3.0 PLUS cleared under K151912 with respect to the indications for use, target populations, treatment method, and technological characteristics.

-END-