December 10, 2021

Guilin Woodpecker Medical Instrument Co., Ltd.
% Sonya Lai
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, Block A, Zhongguan Times Square, Liuxian Avenue,
Xili Town, Nanshan District
Shenzhen, Guangdong 518000
China

Re: K203615
Trade/Device Name: Dental scaler and air polisher
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: Class II
Product Code: ELC, KOJ
Dated: November 11, 2021
Received: November 22, 2021

Dear Sonya Lai:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203615

Device Name
Dental Scaler and Air Polisher

Indications for Use *(Describe)*
The dental scaler and air polisher, Model PT-A, is intended for use in dental cleaning, periodontal (gum) therapy and polishing. The device polishes the teeth and removes calculus deposits and stains from pits, grooves, interproximal spaces, or smooth surfaces of teeth. By attaching the ultrasonic handpiece with different scaling tips, the device could fulfill the following functions:
① Scaling
Removal of supragingival calculus; Removal of stains
② Endo
Preparation, cleaning and irrigation of root canals; Retrograde preparation of root canals
Condensing gutta-percha; Removal of crown, bridges and restorations
③ Restorative
Cavity preparation; Luting inlays and onlays; Condensing of amalgams
④ Perio
Scaling and root planing; Periodontal treatments

By using air polishing handpiece attached with corresponding nozzles, the device could fulfill the following functions
• Removing dental plaque
• Surface preparation before bonding/cementation of inlays, onlays, crowns and veneers
• Tooth surface preparation before placing the composite restoration
• Cleaning before sticking orthodontic brackets
• Effectively removing plaque for orthodontic patients
• Cleaning the implant fixture before loading
• Stain removal for shade determination
• Removing plaque before fluoride treatment
• Removing plaque before whitening procedure

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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510(k) Summary

1. Contact Details

1.1 Applicant information

Applicant Name	Guilin Woodpecker Medical Instrument Co., Ltd.
Address	Information Industrial Park, Guilin National High-Tech Zone, Guilin, Guangxi, 541004, P.R. China
Phone No.	+86 773 2350532
Contact person	Yiwei Wang
Date Prepared	Nov 15, 2021
Website	http://www.glzmn.com/

1.2 Submission Correspondent

卓远天成	Shenzhen Joyantech Consulting Co., Ltd 1713A, 17th Floor, Block A, Zhongguan Times Square, Liuxian Avenue, Xili Town, Nanshan District, Shenzhen, Guangdong, 518000, China
Phone No.	+86-755-86069197
Contact person	Sonya Lai; Field Fu
Contact person's e-mail	sonya@cefda.com; field@cefda.com
Website	http://www.cefda.com

2. Device information

Trade name	Dental Scaler and Air Polisher
Common name	Ultrasonic scaler
Model	/
Classification	Ⅱ
Classification name	Scaler, ultrasonic
Product code	ELC; KOJ
Regulation No.	872.4850

3. Legally Marketed Predicate Device

Trade Name	EMS AIR-FLOW MASTER PLEZON (Primary Predicate)
510(k) Number	K110173
Product Code	ELC; EFB; EJR
Manufacturer	E.M.S. Electro Medical Systems SA

4. Device Description

The dental scaler and air polisher, Model PT-A, mainly consists of ultrasound scaler system and air polishing system. More specifically, it mainly contains a control module, a display panel with function

keys, water bottle, powder tank, scaling handpiece, air polishing handpiece, scaling tips, sand blasting nozzle, foot pedal and power adapter.

The device generates ultrasonic waves intended for dental applications such as scaling, root canal irrigation and periodontal preparation. For the ultrasonic system, a sinusoidal electrical signal is generated and delivered to the 'piezoelectric ceramic' located inside the ultrasonic handpiece. The electrical signal is converted into mechanical vibrations and propagated to the distal end of the handpiece. For air polishing system, the powder in the powder tank is driven by air pressure to flow into the nozzle attached with the air polishing handpiece and mixed with air and water to blast the teeth. By attaching the ultrasonic handpiece with appropriate scaling tips, the device could fulfill scaling, restorative, endodontic and periodontal treatment. However, by attaching the corresponding nozzle to the air polishing handpiece, the device could remove calculus, stains, plaques and polish the teeth.

The device is powered by a power adapter with input of 110V~ 50Hz/60Hz 800mA and output of 25V~ 50Hz/60Hz 2.8A. The ultrasonic handpiece, air polishing handpiece with or without non-disposal stainless steel sand blasting nozzles, and scaling tip are provided non-sterile, which will be sterilized by the user before use.

5. Intended Use/Indication for Use

The dental scaler and air polisher, Model PT-A, is intended for use in dental cleaning, periodontal (gum) therapy and polishing. The device polishes the teeth and removes calculus deposits and stains from pits, grooves, interproximal spaces, or smooth surfaces of teeth.

By attaching the ultrasonic handpiece with different scaling tips, the device could fulfill the following functions:

① Scaling
- Removal of supragingival calculus
- Removal of stains

② Endo
- Preparation, cleaning and irrigation of root canals
- Retrograde preparation of root canals
- Condensing gutta-percha
- Removal of crown, bridges and restorations

③ Restorative
- Cavity preparation
- Luting inlays and onlays
- Condensing of amalgams

④ Perio
- Scaling and root planing
- Periodontal treatments

However, by using air polishing handpiece attached with corresponding nozzles, the device could fulfill the following functions：

- Removing dental plaque
- Surface preparation before bonding/cementation of inlays, onlays, crowns and veneers
- Tooth surface preparation before placing the composite restoration
- Cleaning before sticking orthodontic brackets
- Effectively removing plaque for orthodontic patients
- Cleaning the implant fixture before loading
- Stain removal for shade determination
- Removing plaque before fluoride treatment
- Removing plaque before whitening procedure

6. Substantial Equivalence Comparison

Item	**Proposed Device:** Dental Scaler and Air Polisher **(K203615)**	**Predicate Device:** EMS AIR-FLOW MASTER PLEZON **(K110173)**	**Variations**
Product Code	ELC	ELC	Same
Subsequent Product Code	KOJ	EFB, EJR	Same
Regulation number	872.4850	872.4850	Same
Regulation Generic Name	Ultrasonic scaler	Ultrasonic scaler	Same
Intended Use/indication for use	The dental scaler and air polisher, Model PT-A, is intended for use in dental cleaning, periodontal (gum) therapy and polishing. The device polishes the teeth and removes calculus deposits and stains from pits, grooves, interproximal spaces, or smooth surfaces of teeth. By attaching the ultrasonic handpiece with different scaling tips, the device could fulfill the following functions: *Scaling: Removal of supragingival calculus; Removal of stains *Endo: Preparation, cleaning and irrigation of root canals; Retrograde preparation of root	The AIR-FLOW MASTER PIEZON combines the functions of an ultrasonic scaler and air-polishing unit within a single chassis. The AIR-FLOW MASTER PIEZON 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 * Releasing crowns, bridges, inlays, and posts as well as condensing gutta percha * Plugging for amalgam condensation " Amalgam burnishing	Same

Item	**Proposed Device:** Dental Scaler and Air Polisher **(K203615)**	**Predicate Device:** EMS AIR-FLOW MASTER PLEZON **(K110173)**	**Variations**
	canals; Condensing gutta percha; Removal of crown, bridges and restorations *Restorative: Cavity preparation; Luting inlays and onlays; Condensing of amalgams *Perio: Scaling and root planing; Periodontal treatments; However, by using air polishing handpiece attached with corresponding nozzles, the device could fulfill the following functions：Removing dental plaque; Surface preparation before bonding/cementation of inlays, onlays, crowns and veneers; Tooth surface preparation before placing the composite restoration; Cleaning before sticking orthodontic brackets; Effectively removing plaque for orthodontic patients; Cleaning the implant fixture before loading; Stain removal for shade determination; Removing plaque before fluoride treatment; Removing plaque before whitening procedure	* Preparing, cleaning and irrigating root canals * Cavity preparation * Cementing inlays and onlays * Retrograde preparation of root canals; The AIR-FLOW MASTER PIEZON 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 AIR-FLOW MASTER PIEZON 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 AIR-FLOW MASTER	

Item	**Proposed Device:** Dental Scaler and Air Polisher **(K203615)**	**Predicate Device:** EMS AIR-FLOW MASTER PLEZON **(K110173)**	**Variations**
		PLEZON is also intended for use as an air-polisher in patients suffering from periodontal disease. The AIR-FLOW MASTER PIEZON is indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment.	
Function	ultrasonic scaling and air polishing	ultrasonic scaling and air polishing	Same
Mechanism of action	• Ultrasonic energy • Projection of water/air/powder mixture	• Ultrasonic energy • Projection of water/air/powder mixture	Same
Anatomical site	Teeth and soft tissues in the mouth	Teeth and soft tissues in the mouth	Same
Treatment site	Subgingival and supragingival	Subgingival and supragingival	Same
Components	• Control Unit • Powder tank • Water bottle • Foot pedal • Ultrasonic Handpiece • Air polishing Handpiece (AP-1, AP-2)	• Control Unit • Powder chamber • Irrigation liquid bottle • Foot pedal • Piezon Handpiece LED • AIR-FLOW Handpiece • PERIO-FLOW Handpiece	Equivalent
Contact duration	Limited ≤ 24 hours	Limited ≤ 24 hours	Same
Operating Mode	Continuous Operation	Continuous Operation	Same
Electric power supply	• 110 VAC • 50-60Hz	• 100-240 VAC • 50-60Hz	Similar[#1]
Ultrasound Max output power	8W	8W	Same

Item	**Proposed Device:** Dental Scaler and Air Polisher **(K203615)**	**Predicate Device:** EMS AIR-FLOW MASTER PLEZON **(K110173)**	**Variations**
Ultrasound Frequency	30±5kHz	24 to 32 kHz	Similar[#2]
Flow rate adjustment	Touch panel	Touch panel	Same
Water delivery system	• One irrigating liquid bottle for ultrasonic scaling treatment and air polishing • 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 air polishing treatment	Similar[#3]
Foot pedal	Wired, 4 functions	Wired, 4 functions	Same
Software	Yes	Yes	Equivalent
Biocompatibility	Biocompatible	Biocompatible	Same
Sterility	scaling tips, nozzles and handpieces are resterilized to reuse	scaling tips, nozzles and handpieces are resterilized to reuse	Same
Shelf life	Unrestricted	Unrestricted	Same

The subject device and the predicate device have a slight difference in the following aspects. We discuss below to make it clear that these minor differences are not issues/concerns for the equivalency of the subject device and predicate device and don't affect the performance of safety and effectiveness of the subject device.

Similar**#1** **Electric power supply**: the predicate device is supplied with power of 110vac, 50-60Hz while the subject device is supplied with 100-240Vac, 50-60Hz. This power difference is for the device to be compatible with different power supply system located in different areas/countries. The difference should not affect the device's performance of safety and efficacy.

Similar**#2** **Ultrasound frequency**: the predicate device has an ultrasound frequency of 30±5kHz compared to the 24 to 32 kHz of predicate device. The ultrasound frequency of subject device varies from 25kHz to 35kHz, which falls within the range or almost the same as predicate device. Plus the subject device passed related requirements for safety and efficacy. Thus this minor difference does not raise any new issues or concerns of safety or effectiveness.

Similar[#3] **Water delivery system:** the subject device has an irrigating water bottle for ultrasonic scaling treatment and air polishing. It also is connected to external water supply for both ultrasonic scaling and air polishing. As a comparison, the predicate device has an irrigating water bottle for ultrasonic scaling system and is connected to external water supply for air polishing treatment. Even though the subject device has one more choice of water sources for either scaling or polishing treatment than the predicate device, in both of the devices, the scaling system and the air polishing system are all provided with water in order for the device to work properly. The difference of water supply choice doesn't affect the subject device's performance of safety and efficacy.

7. Non-clinical Testing

The subject device conforms to the following standards:

IEC 60601-1:2005+CORR.1:2006+CORR.2007+A1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance

IEC 60601-1-2:2014 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances-Requirements And Tests

IEC 80601-2-60:2012 Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment

ISO 10993-5:2009 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity.
Biocompatibility testing of in vitro cytotoxicity was performed to verify the equivalent safety of the materials that are in direct contact with mucosal membrane and teeth in the mouth, and skin including ultrasonic handpiece, air polishing handpiece, scaling tips and sand blasting nozzle. The testing was also carried out for materials that are in indirect contact with the same sites including the device components/parts involved in contacting irrigating water or pressurized air. The testing results indicate the materials meet the requirements.

ISO 10993-10:2010 Biological Evaluation of Medical Devices- Part 10: Tests for Irritation and Skin Sensitization
Biocompatibility testing for Irritation and Skin Sensitization was performed to verify the equivalent safety of the materials that are in direct contact with mucosal membrane and teeth in the mouth, and skin including ultrasonic handpiece, air polishing handpiece, scaling tips and sand blasting nozzle. The testing was also carried out for materials that are in indirect contact with the same sites including the device components/parts involved in contacting irrigating water or pressurized air. The testing results indicate that the materials meet the requirements.

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

Performance comparison test involves two standards: ISO 18397: 2016 Dentistry - Powered scaler and IEC 61205: 1993 Ultrasonics - Dental descaler systems - Measurement and declaration of the output characteristics.

Performance comparison test performed on subject device and predicate device aims to support the substantial equivalence of the subject device to the predicate device. Test's setup and execution was in accordance with applicable standards. Results of the testing demonstrate the compliance to the standards and comparable performance between subject device and predicate device.

8. Clinical testing

The substantial equivalence of the subject device to the predicate device doesn't depend on clinical testing, thus clinical testing was not performed for the proposed device.

9. Other information (such as required by FDA guidance/Test)

N/A

10. Conclusions Drawn from Non-Clinical and Clinical Tests

The Dental Scaler and Air Polisher is substantially equivalent to the legally marketed predicate EMS AIR-FLOW MASTER PIEZON (K110173).