September 22, 2023

Foshan COXO Medical Instrument Co., Ltd.
℅ Ray Wang
Official Correspondent
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, Beijing 102401
China

Re: K220179
Trade/Device Name: High-Speed Air Turbine Handpieces/Straight Handpieces/Geared Angle Handpieces/Air Motors
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EFB, EGS
Dated: September 1, 2023
Received: September 1, 2023

Dear Ray Wang:

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,

FDA Bobak Shirmohammadi -S

For Michael E. Adjodha, M. ChE., CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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)*
K220179

Device Name
High-Speed Air Turbine Handpieces/Straight Handpieces/Geared Angle Handpieces/Air Motors

Indications for Use *(Describe)*

High-Speed Air Turbine Handpieces:
It is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.

Straight Handpieces:
It is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.

Geared Angle Handpieces:
It is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.

Air Motors:
It is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.

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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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K220179

1. Date of Preparation

   09/21/2023

2. Sponsor

Foshan COXO Medical Instrument Co., Ltd.
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3. Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: High-Speed Air Turbine Handpieces/Straight Handpieces/Geared Angle Handpieces/ Air Motors
Common Name: Dental Handpiece and Accessories
Model(s):
High-Speed Air Turbine Handpieces
CX207, CX207-G, CX207-2, CX207-A, CX207-A-2, CX207-B, CX207-B-2, CX207-C, CX207-C-2, CX207-W, CX207-W-2

Straight Handpieces
CX235-2, CX235-2A, CX235-2B, CX235-2F, CX235-2G, CX235-2C, CX235- 2S2

Geared Angle Handpieces
CX235-1B, CX235-1C, CX235-1F, CX235-1G, CX235C1, CX235C2, CX235C3, CX235C4, CX235C5, CX235C6, CX235C7, CX235C8, CX235-2S, CX235-2S1

Air Motors:
CX235-3B, CX235-3F, CX235-3C

Regulatory Information:
Regulation Name: Dental Handpiece And Accessories
Classification: I;
Product Code: EFB;
Additional Product Code: EGS;
Regulation Number: 21 CFR 872.4200;
Review Panel: Dental;

Indications for Use Statement:

High-Speed Air Turbine Handpieces:
It is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.

Straight Handpieces:
It is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.

Geared Angle Handpieces:
It is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.

Air Motors:

It is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.

5. Device Description

The proposed device is used to hold rotary instruments such as burs and drills for cutting, grinding, and drilling operations. The dental handpieces are hand-held instruments driven by air motor, thus driving the rotation of dental attachments for the purpose of drilling and tooth cutting. Some models include an electric connection to power an LED light

6. Identification of Predicate Device

Primary Predicate Device:
510(k) Number: K181691
Product Name: High-Speed Air Turbine Handpiece / Low-Speed Air Turbine Handpiece
Manufacturer: Foshan Wenjian Medical Instrument Co., Ltd.

Reference Device:
510(k) Number: K202786
Product Name: Dental Low-speed Handpieces and Accessories
Manufacturer: MicroP Technology (Taiwan), Inc.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ANSI/AAMI ES60601-1:2005/(R)2012 And 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 compatibility- Requirements and tests;
- IEC 80601-2-60: 2019, 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 Device-Part 5: Tests for Vitro cytotoxicity;
- ISO 10993-10:2021, Biological Evaluation of Medical Device-Part 10: Test for irritation and delay-type hypersensitivity;
- ISO 10993-23:2021, Biological Evaluation of Medical Device – Part 23: Tests for irritation;
- ISO 10993-11:2017, Biological Evaluation of Medical Device – Part 11: Test for systemic toxicity;
- Pyrogen Study in Rabbits using USP General Chapter <151> Pyrogen Test;
- ISO 14457 Second edition 2017-10 Dentistry - Handpieces and motors;

- ISO 17664 Second edition 2017-10 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices
- ISO 17665-1 First edition 2006-08-15 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 9168 Third edition 2009-07-15 Dentistry - Hose connectors for air driven dental handpieces

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 7-3 General Comparison

ITEM	Proposed Device	Primary Predicate Device	Reference Device	Remark
Manufacturer	Foshan COXO Medical Instrument Co., Ltd.	Foshan Wenjian Medical Instrument Co., Ltd.	MicroP Technology (Taiwan), Inc.	--
Device Name	High-Speed Air Turbine Handpieces/ Straight Handpieces/ Geared Angle Handpieces/ Air Motors	High-speed air turbine handpiece Low-speed air turbine handpiece	Dental Low-speed Handpieces and Accessories	--
Model	High-Speed Air Turbine Handpieces:CX207, CX207-G, CX207-2, CX207-A, CX207-A-2, CX207-B, CX207-B-2, CX207-C, CX207-C-2, CX207-W, CX207-W-2 Straight Handpieces: CX235-2, CX235-2A, CX235-2B, CX235-2F, CX235-2G, CX235-2C, CX23 5- 2S2 Geared Angle Handpieces: CX235-1B, CX235-1C, CX235-1F, CX235-1G, CX235C1, CX235C2, CX235C3, CX235C4, CX235C5, CX235C6, CX235C7, CX235C8, CX235-2S, CX235-2S1 Air Motors:CX235-3B, CX235-3F, CX235-3C	Dental High-speed Turbine Handpiece (WJ-114, WJ- 112, WJ-124, WJ -122, WJ- 134, WJ -132, WJ - 144, WJ -142, WJ -154, WJ - 152, WJ -164, WJ -162) Dental Low-speed Turbine Handpiece (WJ-414, WJ- 412, WJ-424, WJ-422)	Contra-angle Handpieces: G25, G25L, G23 Straight Handpieces: G65, G65L, G63	--
Product Code	EFB, EGS	EFB, EGS	EFB, EGS	SAME
Regulation No.	21 CFR 872.4200	21 CFR 872.4200	21 CFR 872.4200	SAME
Class	I	I	I	SAME
Indication	High-Speed Air Turbine Handpieces: It is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth. Straight Handpieces: It is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.	Dental High-speed Turbine Handpiece (WJ-114, WJ- 112, WJ-124, WJ -122, WJ- 134, WJ -132, WJ - 144, WJ -142, WJ -154, WJ - 152, WJ -164, WJ -162) is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root	MicroP Dental Low-speed Handpieces and Accessories is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth. All the devices are designed for use by a trained professional in the field of general dentistry	SAME

	Geared Angle Handpieces: It is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth. Air Motors: It is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.	canal preparations and polishing teeth. Dental Low-speed Turbine Handpiece (WJ-414, WJ- 412, WJ-424, WJ-422) is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.		
Air/water ports	2/4/6 ports	2/4 ports	up to four	DIFFERENT 1
Fiberoptic Glass Rod	CX207-G, CX235-1C, CX235C7	Included in model WJ-162, WJ-164, WJ-424 and WJ- 422Disposable	Included in model G25Land G65L	SAME
Accessories	NA	NA	NA	SAME
Composition of material	Copper (chromium plating), aluminum , rubber and stainless steel	Stainless steel, Brass, Aluminum, Titanium	Stainless steel, Aluminum Alloy	DIFFERENT 2
Chuck	Push button, Screw	Push button, Screw	Push button	SAME
Bur extraction force	22N	28N	/	DIFFERENT 3
Maximum air pressure	High-speed Air Turbine Handpieces:0.2-0.25Mpa Straight handpiece & Geared Angle handpiece & Air Motors:0.245MPa ~0.3925MPa	Dental High-speed Turbine Handpiece: 200kPa ~ 250kPa (29.01 psi~ 36.25 psi) Dental Low-speed Turbine Handpiece: 245 ~ 392 kPa (35.53 psi~ 56.85 psi)	0.248-0.296MPa (36psi~43psi)	SAME

Maximum water pressure	High-Speed Air Turbine Handpieces: 0.2-0.25Mpa Straight handpiece & Geared Angle handpiece & Air Motors:0.245MPa ~0.3925MPa	Dental High-speed Turbine Handpiece: 200kPa ~ 250kPa (29.01 psi~ 36.25 psi) Dental Low-speed Turbine Handpiece: 245 ~ 392 kPa (35.53 psi~ 56.85 psi)	0.248-0.296MPa (36psi~43psi)	SAME
Speed in rpms	High-speed Air Turbine Handpieces:280000 ~ 450000 Straight handpiece &Geared Angle handpiece &Air Motors:＜40000rpm	Dental High-speed Turbine Handpiece: 300,000rpm ~ 400,000rpm Dental Low-speed Turbine Handpiece: 18,000 ~ 20,000 rpm	＜40000rpm	DIFFERENT 4
Conformance with standards for shanks	Type 3 per ISO 1797-1	Type 3 per ISO 1797-1	/	SAME
Coupling dimensions	Complied with ISO 3964	Complied with ISO 3964	/	SAME
Hose connections	Type 1 for 2-hole model / Type 2 for 4- hole model/Type 3 for 6-hole model	Type 1 for 2-hole model / Type 2 for 4- hole model	/	SIMILAR
Lubricant	The lubricants approved by FDA, such as DO-ALL Dental Handpiece Lubricant (K073353).	The specified lubricant, type “PANA SPRAY Plus” manufactured by NAKANISHI INC (cleared in K163483), must be used during routine maintenance.	MicroP Halley Spray	SIMILAR
Compliance Standards	Complied with ISO 10993- 5, ISO 10993-10, ISO 10993-23, ISO 10993-11, USP <151> Pyrogen Testing, IEC 60601-1, IEC 60601-1-2, IEC 80601- 2-60, ISO14457, ISO 17665-1, ISO 17664, ISO 9168	Complied with ISO 10993- 5, ISO 10993-10, IEC 60601-1, IEC 80601- 2-60, ISO14457, ISO 17665, ISO 11138, ISO 11607, ISO 17664	Complied with ISO 10993- 5, ISO 10993-10, ISO14457	SAME

10. Substantially Equivalent (SE) Conclusion

DIFFERENT 1

The difference between proposed device and predicate device is Air/water ports, which is use for connection, the difference does not affect the safety and effectiveness of proposed device. Based on the nonclinical tests performed, the proposed device is as safe, as effective, and performs as well as the legally marketed predicate device.

DIFFERENT 2

The Handpiece is tissue-contacting, so it is tested accordance with the requirements of ISO 10993-1 and guidelines. The test results meet the requirements. Based on the biological test results, the proposed device is as safe, and performs as well as the legally marketed predicate device.

DIFFERENT 3

The difference between proposed device and predicate device is bur extraction force. The ISO 14457 required the bur extraction force shall be at least 22 N for Type 5. Based on the nonclinical tests performed, the proposed device meets the standard and is as safe, as effective, and performs as well as the legally marketed predicate device.

DIFFERENT 4

The difference between proposed device and predicate device is Speed. The proposed device's speed range is covered by the Predicate Device's speed range. Therefore, the proposed device's speed range can meet the use requirement. We tested as ISO 14457, based on the nonclinical tests performed, the proposed device is as safe, as effective, and performs as well as the legally marketed predicate device.

Conclusion: Based on the comparison of technological characteristics, demonstrated through bench testing and intended use, the proposed device is substantially equivalent to the predicate device.