May 26, 2020

Foshan Wenjian Medical Instrument Co., Ltd.
% Cassie Lee
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
Suite 306, Kecheng Mansion, No.121 Science Road, Guangzhou Science Park
Guangzhou, Guangdong, 510663
CHINA

Re: K181691
Trade/Device Name: High-speed air turbine handpiece / Low-speed air turbine handpiece
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: Class I, reserved
Product Code: EFB, EGS
Dated: April 9, 2020
Received: April 27, 2020

Dear Cassie Lee:

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,

for Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K181691

Device Name
High-speed air turbine handpiece / Low-speed air turbine handpiece

Indications for Use *(Describe)*
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 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

K181691

510(k) Summary
Date Prepared: May 22, 2020

1. Submitter's Information

Name of Sponsor: Foshan Wenjian Medical Instrument Co., Ltd.

Address: Third Floor, No.3, Jiebian Industrial Zone, LuoCun, ShiShan Town, Nanhai, Foshan City, Guangdong, China

Contact Name (Title): Wen Huang (Manager) Telephone No.: 86-757-81801258

Email: 1191837402@qq.com

Application Correspondent:

Contact Person: Ms. Cassie Lee

Guangzhou GLOMED Biological Technology Co., Ltd.

Address: Suite 306, Kecheng Mansion, No.121 Science Road, Guangzhou Science Park, Guangzhou 510663, China

Tel: +86-20-61099984

Email: regulatory@glomed-info.com

2. Subject Device Information:

Common Name: Dental Handpiece and Accessories

Trade Name: High-speed air turbine handpiece / Low-speed air turbine handpiece Model:

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) Classification Name: Dental Handpiece and Accessories

Review Panel: Dental Product Code: EFB, EGS Regulation Class: 1

Regulation Number: 21 CFR 872.4200

3. Predicate Device Information:

Primary Predicate: (K170229)

Company Name: Guangdong JINME Medical Technology Co., Ltd.

Common Name: Dental Handpiece and Accessories

Trade Name: Dental High-speed Turbine Handpiece

Product Code: EFB

Regulation Class: 1

Reference Device 1: (K170236)

Company Name: Guangdong JINME Medical Technology Co., Ltd.
Common Name: Dental Handpiece and Accessories
Trade Name: Dental Low-speed Turbine Handpiece
Product Code: EFB, EGS
Regulation Class: 1

Reference Device 2: (K141886)
Company Name: Modern Korea Co., Ltd. Trade Name: MDK Handpieces
Classification Name: Dental Handpiece and Accessories
Product Code: EFB
Regulation Class: 1

4. Device Description

- **Dental High-speed Turbine Handpiece**

The Dental High-speed Turbine Handpiece is the dental clinic, hospital treatment for patients with tooth disease tools, which is an instrument for drilling, grinding, repairing. It composed of handpiece and a connector, including models WJ-114, WJ-112, WJ-124, WJ -122, WJ-134, WJ -132, WJ -144, WJ -142, WJ -154, WJ -152, WJ -164, WJ -162.

For the model name which including: WJ represent for branch name.
WJ-1XX represent for Dental High-speed Turbine Handpiece;
WJ-XX2 represent for model which included 2-hole (drive air and water holes);
WJ-XX4 represent for model which included 4-hole coupling (drive air, exhaust air, spray air and spray water holes);
Handpiece are able to run 300000 to 400000 rpm.

Handpiece and adaptors can bear steam disinfection at 135°C. The scope of application: for dental professional use only.
Lubricant should be used during routine maintenance (e.g. after each patient use and prior to sterilization).
In order to avoid the risk, user must buy and use specified lubricant type “PANA SPRAY Plus” manufactured by NAKANISHI INC (cleared in K163483).

- **Dental Low-speed Turbine Handpiece**

The Dental Low-speed Handpiece is the dental clinic, hospital treatment for patients with tooth disease tools, which is an instrument for drilling, grinding, repairing. It composed of handpiece and a connector, including low speed air motor, straight handpiece and geared angle handpiece, for the model WJ-414, WJ-412, WJ-424, WJ-422

The gear ratios of handpieces have a various gear ratio (for different geared angle handpiece) (1:1 (constant), 20:1 (speed reduction) and 1:5 (speed increase));
The handpieces have maximum Forward rotation speed 19000 rpm and maximum Reverse rotation speed of 18000 rpm.
The air motors are capable of running up to a speed of 22000 rpm, but different at different pressure of air supply.
Handpiece and adaptors can bear steam disinfection at 135°C. Coupling is the accessory for handpiece to connect with tubes of dental unit. It could be divided into three types. It included 2-hole (drive air and water holes) and 4-hole coupling (drive air, exhaust air, spray air and spray water holes). The use of the coupling of handpiece is due to the number of tubes of dental unit. The scope of application: for dental professional use only.
Lubricant should be used during routine maintenance (e.g. after each patient use and prior to sterilization).
In order to avoid the risk, user must buy and use specified lubricant type “PANA SPRAY Plus” manufactured by NAKANISHI INC (cleared in K163483).

5. Intended Use / Indications for Use

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 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.

6. Test Summary

High-speed air turbine handpiece / Low-speed air turbine handpiece is designed, tested and will be manufactured in accordance with both mandatory and voluntary standards. Performance testing was provided including:

- Cytotoxicity, sensitization, and irritation biocompatibility test according to ISO 10993-5 and ISO 10993-10 standards
- Performance test according to ISO 14457:2012 standards.
- Medical electrical equipment test according to IEC 60601-1, IEC 80601-2-60 standards
- Sterilization and cleaning validation per ISO 17665-1, ISO 17665-2, ASTM ST79, and the FDA Guidance Document “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling”

The result of tests indicates that the Dental Handpiece and Accessories has substantial equivalent performance as the legally marketed predicate device.

7. Comparison to predicate device and conclusion

Elements of Comparison	Subject Device	Primary Predicate	Reference Device 1	Reference Device 2	Remark
Manufacturer	Foshan Wenjian Medical Instrument Co., Ltd.	Guangdong JINME Medical Technology Co., Ltd.	Guangdong JINME Medical Technology Co., Ltd.	Modern Korea Co. Ltd.	--
Device Name	High-speed air turbine handpiece / Low-speed air turbine handpiece	Dental High-speed Turbine Handpiece	Dental Low-speed Turbine Handpiece	MDK Handpieces	--
Model	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)	T, S, M, TU, SU, MU, TP, SP, TUQ, TUP, SUP, SUQ, TUL, SUL, TUQL, SUQL, TUQP, SUQP, 45- T,45-TU,45-TUQ	LN, L	--	--
510(k) Number	K181691	K170229	K170236	K141886	--
Product Code	EFB, EGS	EFB	EFB, EGS	EFB	SE
Indications for Use& Intended Use	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 canal preparations and polishing teeth. Dental Low-speed	Dental High-speed Turbine Handpiece 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 Low-speed Turbine Handpiece is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.	MDK high-speed handpieces are used for the removal of carious material, reducing of hard tooth structure, cavity and crown preparations, removal of fillings, processing and finishing tooth preparations, restorations,	SE Note 1

	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.			and for polishing teeth. MDK low-speed handpieces used for teeth cutting, cavity and crown preparation, restorations and polishing teeth. All the devices are designed for use by a trained professional in the field of general dentistry.	
Air/water ports	2/4 ports	2/4 ports	2/4 ports	Up to four	SE
Fiberoptic Glass Rod	Included in model WJ-162, WJ-164, WJ-424 and WJ-422	N/A	N/A	Yes (11 models) No (10 models)	SE Note 2
Dimensions	Refer to table 1	N/A	N/A	N/A	SE Note 3
Accessories	N/A	N/A	N/A	High -speed handpieces Wrench, Connector (for inserting lubricant) Low-speed handpieces Head opener for the latch type, Connector for inserting lubricant, External Spray Tubing with nozzle	SE Note 4
Composition of material	Stainless steel, Brass, Aluminum, Titanium	Stainless steel, Brass, Aluminum, Titanium	Stainless Steel, Brass, Titanium	Stainless steel and titanium	SE
Chuck	Push button, Screw	Push button, Screw	Push button Latch-type chuck	push button, latch, screw, snap-on or tip-lock chuck options	SE

Bur extraction force	28N	28N	--	30N	SE
Maximum air pressure	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)	177kPa ~ 301kPa (25.67 psi~ 45.66 psi)	245 ~ 392 kPa (35.53 psi~ 56.85 psi)	36psi to 43psi	SE Note 3
Maximum water pressure	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)				
Speed in rpms	Dental High-speed Turbine Handpiece: 300,000rpm ~ 400,000rpm Dental Low-speed Turbine Handpiece: 18,000 ~ 20,000 rpm	300,000rpm ~ 400,000rpm	18,000 ~ 22,000 rpm	High -speed handpieces 320,000 ~ 400,000rpm Low-speed handpieces Up to 20,000 rpm	SE Note 3
Conformance with standards for shanks	Type 3 per ISO 1797-1	Type 3 per ISO 1797-1	Type 3 per ISO 1797-1	N/A	SE
Coupling dimensions	Complied with ISO 3964	N/A	Complied with ISO 3964	N/A	SE
Hose connections	Type 1 for 2-hole model / Type 2 for 4-hole model	Type 1 for 2-hole model / Type 2 for 4- hole model	Type 1 for 2-hole model / Type 2 for 4-hole model	N/A	SE
Lubricant	The specified lubricant, type “PANA SPRAY Plus” manufactured by NAKANISHI INC (cleared in K163483), must be used during routine maintenance.	The specified lubricant, type “PANA SPRAY Plus” manufactured by NAKANISHI INC (cleared in K163483), must be used during routine maintenance.	The specified lubricant, type “PANA SPRAY Plus” manufactured by NAKANISHI INC (cleared in K163483), must be used during routine	Pana-Spray made by NSK(K052700)	SE Note 5

			maintenance.		
Compliance Standards	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	Complied with ISO 10993-5, ISO 10993-10, ISO14457	Complied with ISO 17665, ISO 11138, ISO 11135, ISO 11607, ISO 17664, and USP 30-NF 25,ISO 14457, ISO 10993-5	SE Note 6

Comparison in Detail

Note 1:

Although the subject devices are a little difference from predicate devices in “Intended Used”, but it’s the combination of predicate devices K170229 and K170236. And it’s the same with K141886. So, the difference will not raise any substantial equivalence issue.

Note 2:

Although the subject devices are a little difference from predicate devices in “Fiberoptic” glass rod to transmit light, but the subject devices are compliance with safety standard IEC 60601-1 instead. But it’s the same with K141886. So the difference will not raise any substantial equivalence issue.

Note 3:

Although the subject devices are a little difference from predicate devices in “Dimensions”, “Maximum air pressure”, “Maximum water pressure” and “Speed in rpms”, the subject devices are it’s the features combination of predicate devices K170229 and K170236 and K141886. So, the difference will not raise any substantial equivalence issue.

Note 4:

The subject devices are a little difference from predicate devices in “Accessories” with K141886, but it’s the same with the predicate devices K170229 and K170236. The accessories in predicate devices are mainly tools for cleaning handpieces. Not part of predicate devices. So the accessories do not affect the product performance. So, the difference will not raise any substantial equivalence issue.

Note 5:

The subject devices are a little difference from predicate devices in “Lubricant”, but the Lubricant is only used for lubrication. As long as it meets the requirements and is FDA cleared, Lubricant can achieve lubrication.
Therefore, which brand of Lubricant is used does not affect the performance of the device. So, the difference will not raise any substantial equivalence issue.

Note 6:
The common sterilization method of dental handpieces is steam sterilization, because the structure and material characteristics of dental handpieces:. The common dental handpieces sterilization method in the market is also steam sterilization. Therefore, ISO 17665 is applicable standard for verification of steam sterilization. The sterilization method adopted by the subject device is the commonly used steam sterilization. Because the sterilization USES steam, there is no other harmful residue after sterilization. Therefore, there is no need to refer to ISO 11135 and USP 30-NF25 for subject device. So, the difference will not raise any substantial equivalence issue.

Finial conclusion:

The subject device 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) has all features of predicate devices. Thus, the subject device is substantially equivalent to the predicate device.