Guangdong JINME Medical Technology Co., Ltd.
% Cassie Lee
Vice President
Guangzhou GLOMED Biological Technology Co., Ltd.
Suite 306, Kecheng Mansion, No.121 Science Road,
Guangzhou Science Park
Guangzhou, 510663 CN

November 8, 2017

Re: K170229
Trade/Device Name: Dental High-speed Turbine Handpiece
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I
Product Code: EFB
Dated: September 30, 2017
Received: October 10, 2017

Dear Cecilia Ceng:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K170229

Device Name
Dental High-speed Turbine Handpiece

Indications for Use *(Describe)*
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.

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 K170229

1. Submitter's Information

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

Establishment registration number: Applying

Address: A15, New Light Source Industrial Base, Nanhai District, Foshan, Guangdong, China

Name of contact person: Kristi Yang

Title: Manager

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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

E-mail: regulatory@glomed-info.com

2. Subject Device Information:

Type of 510(k) Submission: Traditional

Common Name: Dental Handpiece

Trade Name: Dental High-speed Turbine Handpiece

Models: T, S, TU, SU, TP, SP, TUQ, TUP, SUP, SUQ, TUQP, SUQP

Classification Name: Dental Handpiece and accessories

Product Code: EFB

Regulation Number: 21CFR 872.4200

Regulation Class: 1

3. Predicate Device Information:

Predicate Device: K152146

Company Name: Codent Technical Industry Co., Ltd.

Trade Name: High Speed Handpiece and Accessories

Common Name: Dental Handpiece and Accessories

Product Code: EFB

Reference Device: K141886

Company Name: Modern Korea Co., Ltd.

Trade Name: MDK Handpieces

Common Name: Dental Handpiece and Accessories

Product Code: EFB

Reference Device: K163483

Company Name: NAKANISHI, INC.

Trade Name: Pana Spray Plus

Common Name: Dental Handpiece and Accessories

Product Code: EFB

4. Device Description

The Dental High-speed Turbine Handpiece is the dental clinic, hospital treatment for patients with tooth disease tools, which is an effective instrument for drilling, grinding, repairing. It composed of handpiece and a connector.

The handle is slide-proof, comfortable and easy to clean. Handpiece and adaptors can bear steam disinfection at 135°C. The head angle can provide better operational vision and angle so that work efficiency can be improved. Cartridges have high precision when rotating; cartridges have low noise and high efficiency. 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 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

Dental High-speed Turbine Handpiece is designed, tested and will be manufactured in accordance with both mandatory and voluntary standards, including:

Performance test according to ISO 14457 standard

Biocompatibility test according to ISO 10993-1 standard

Sterilization test according to ISO 17665:2006 and ISO 11134:2003 standards

Reprocessing validation according to FDA guidance document *Dental Handpieces - Premarket Notification [510(k)] Submissions*

The result of tests indicates that the Dental High-speed Turbine Handpiece is substantially equivalent to the legally marketed predicate device.

7. Comparison to predicate device and conclusion

Elements of Comparison	Subject Device	Predicate Device (Primary)	Reference Device	Reference Device	Remark
Manufacturer	Guangdong JINME Medical Technology Co., Ltd.	Codent Technical Industry Co., Ltd.	Modern Korea Co., Ltd.	NAKANISHI, INC.	--
Device Name	Dental High-speed Turbine Handpiece	High Speed Handpieces and Accessories	MDK Handpieces	Pana Spray Plus	--
Model	T, S, TU, SU, TP, SP, TUQ, TUP, SUP, SUQ, TUQP, SUQP	A45 series, A6 series, A5 series, A4 series, A3 series, E-6510 series, E-6500 series, E-6110 series, E-6100 series, HPX series, HPM series, HPK series	--	--	--
510(k) Number	K170229	K152146	K141886	K163483	--
Product Code	EFB	EFB	EFB	EFB	SE

Indications for Use& Intended Use	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.	High Speed Handpieces and Accessories are 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, 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.	PANA SPRAY Plus is a lubricant to be used during routine maintenance of dental and medical surgical handpieces after each patient use and prior to sterilization and is intended for use to clean and lubricate the dental and medical surgical handpieces.	SE Note 4
Operational Modes	Air-powered	Air-powered	Air-powered	--	SE
Water Spray	Single/Triple	Single/Triple	--	--	SE
Type of Chuck	Push button, Screw	Push button	Push button, Latch, Screw, Snap-on or tip-lock chuck options	--	SE Note 1
Composition of Main Materials	Stainless Steel, Brass, Titanium	Stainless steel, Brass, Aluminum, Titanium	Stainless Steel, Titanium	--	SE Note 2
Bur Extraction Force	28N	22N~45N	--	--	SE Note 3
Operating Pressure	177KPa ~ 301KPa	200KPa	--	--	SE Note 3
Rotation Speed	300,000rpm ~ 400,000rpm	350,000rpm ~ 400,000rpm	--	--	SE Note 3

Sterilization	Steam autoclave method	Steam autoclave method	--	--	SE
Compliance Standards	Complied with ISO 10993-5, ISO 10993-10, ISO14457	--	--	--	SE Note 2
Lubricant	The specified lubricant, type “PANA SPRAY Plus” manufactured by NAKANISHI INC (cleared in K163483), must be used during routine maintenance.	--	--	Lubricant “PANA SPRAY Plus” manufactured by NAKANISHI INC	SE Note 4

Comparison in Detail

Note 1:

Although the “Type of Chuck” of subject device is a little different from predicate devices, the predicate K141886 includes all the chunk types (Push Button Type, Screw Type) of subject device. And “Push Button Type” & “Screw Type” are both have safety mechanical performance for air-powered handpiece.

Note 2:

Although the main materials of subject devices are a little difference from predicate devices, the subject devices are compliance with ISO 10993-1.

Note 3:

Although the subject devices are a little difference from predicate devices in Bur Extraction Force, Operating Pressure, Rotation Speed, Compliance Standards; the subject devices are compliance with “ISO 14457:2012 Dentistry - Handpieces and Motors”.

Note 4:

The user need to buy and use the specified lubricant, type “PANA SPRAY Plus” (cleared in K163483) manufactured by NAKANISHI INC, during routine maintenance.

Finial conclusion:

The subject device Dental High-speed Turbine Handpiece (Models: T, S, TU, SU, TP, SP, TUQ, TUP, SUP, SUQ, TUQP, SUQP) has all features of predicate devices. The differences between them do not raise new questions of safety and effectiveness. Thus, the subject device is substantially equivalent to the predicate device.

8. Date of the summary prepared: November 7, 2017