Chapter 6. 510(k) Summary K170236

1. Submitter's Information

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Application Correspondent:

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2. Subject Device Information:

- Type of 510(k) Submission: Traditional
- Common Name: Dental Handpiece
- Trade Name: Dental Low-speed Turbine Handpiece
- Models: LN, L
- Classification Name: Dental Handpiece and accessories
- Product Code: EFB
- Regulation Number: 21CFR 872.4200
- Regulation Class: 1

3. Predicate Device Information:

Predicate Device 1:

- ♦ 510(K) Number: K150798
- ♦ Company Name: Codent Technical Industry Co., Ltd.
- ♦ Trade Name: Low Speed Handpiece and Accessories
- ♦ Common Name: Dental Handpiece and Accessories
- ♦ Product Code: EFB, EGS

Reference Device K141886

- ♦ Company Name: MODERN KOREA Co., Ltd.
- ♦ Trade Name: MDK handpieces - Low-speed 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 Low-speed 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, including low speed air motor, straight handpiece and geared angle handpiece, for the model LN and L. The device description of the Dental Low-speed Handpiece is as following:

The gear ratios of handpieces have various gear ratios (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; refer to section 2.3 for details.

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 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.

6. Test Summary

Dental Low-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

Reprocessing and 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 Low-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 Low-speed Turbine Handpiece	Codent Low Speed Dental Handpieces and Accessories	MDK handpieces - Low-speed handpieces	Pana Spray Plus	--
Model	LN, L	LEIPB1, LEIPA1, A61L, A61, A65L, A65, A11, E-2000, E-4010, E-4000, AI6C, AI2C, E-1110, E-1100	--	--	--
510(k) Number	Applying	K150798	K141886	K163483	--
Product Code	EFB, EGS	EFB, EGS	EFB	EFB	SE
Indications for Use& Intended Use	Dental Low-speed Turbine Handpiece is	Codent Low Speed Dental Handpieces and	MDK low-speed handpieces used for teeth cutting,	PANA SPRAY Plus is a lubricant to be	SE

	intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.	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.	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.	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.	
Operational Modes	Air-powered	Air-powered	Air-powered	--	SE
Type of Chunk	Push button Latch-type chuck	Push button	Push button, latch, screw, snap-on or tip-lock chuck options	--	SE
Composition of Main Materials	Stainless Steel, Brass, Titanium	Stainless Steel, Brass, Titanium	Stainless steel and titanium	--	SE
Operating Pressure	245 ~ 392 KPa	--	36psi to 43 psi	--	SE Note 1
Motor Speed	18,000 ~ 22,000 rpm	25,000rpm	Up to 20,000 rpm	--	SE Note 1
Sterilization	Steam autoclave method	Steam autoclave method	--	--	SE
Compliance Standards	Complied with ISO 10993-5, ISO 10993-10, ISO14457	--	Complied with ISO 10993-5, ISO 10993-10, ISO14457	--	SE Note 1
Lubricant	The specified lubricant, type "PANA SPRAY Plus" manufactured by NAKANISHI INC (cleared in K163483), must be used during routine maintenance.	--	Pana-Spray made by NSK(K052700)	Lubricant "PANA SPRAY Plus" manufactured by NAKANISHI INC	SE Note 3

Comparison in Detail

Note 1:

Although the subject devices are a little difference from predicate devices in Operating Pressure, Motor Speed, Compliance Standards; the subject devices are compliance with “ISO 14457:2012 Dentistry - Handpieces and Motors”. So the difference will not raise any safety or effectiveness issue.

Note 2:

We add lubricant “PANA SPRAY Plus” (cleared in K163483) as additional predicate device. And we need user to buy and use the specified lubricant, type “PANA SPRAY Plus” manufactured by NAKANISHI INC, during routine maintenance.

Note 3:

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 Low-speed Turbine Handpiece (Models: LN, L) has all features of predicate devices. The differences between them do not raise new question of safety and effectiveness. Thus, the subject device is substantially equivalent to the predicate device.

8. Date of the summary prepared: November 21, 2017

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

November 21, 2017

Re: K170236
Trade/Device Name: Dental Low-speed Turbine Handpiece
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I
Product Code: EFB, EGS
Dated: October 24, 2017
Received: November 2, 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

for
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