August 11, 2020

Ningbo HPDOVE Dental Instruments Co., Ltd.
% Charlie Mack
Principal Engineer
IRC
2950 E Lindrick Drive
Chandler, AZ 85249

Re: K193264
Trade/Device Name: Disposable High Speed Air Turbine Handpiece
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class II
Product Code: EFB
Dated: May 20, 2020
Received: May 27, 2020

Dear Charlie Mack:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193264

Device Name
Disposable High Speed Air Turbine Handpiece

Indications for Use *(Describe)*
Disposable high speed air 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.

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K193264

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NINGBO HPDOVE DENTAL INSTRUMENTS CO. LTD.

510(k) Summary (21 CFR §807.92)

Submitter Information:

Submitter Name:	NINGBO HPDOVE DENTAL INSTRUMENTS CO. LTD.
Address:	588 Xiaolin Road, Xiaolin Town, Cixi City, Zhejiang Province, P.R.C. 315321
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Contact Person:	Mr. Liyue Huang Manager
Email:	charliemack@irc-us.com

Date of Preparation: July 20, 2020

Subject Devices :

Trade/proprietary name: Disposable high-speed air turbine handpiece
Model YCX-TOD-PP
Common Name: Disposable high-speed air turbine handpiece
Classification : 21CFR872.4200

Predicate Device:

Trade Name: High-Speed Handpieces and Accessories
510(k) Reference: K152146
Common Name: Handpiece, air-powered, dental
Regulation Number: 21CFR872.4200
Regulatory Class: Class II
Manufacturer: Codent Technical Industry Co. Ltd.

Purpose of Submission

This is a new traditional 510(K) submission of Disposable high-speed air turbine handpiece.

Device Description

The disposable high-speed air turbine handpiece is an air-driven dental handpiece for the use by a trained professional in the field of general dentistry. The device is an ergonomically shaped air-powered handpiece that is disposable. The device features a 4-pin (drive air, exhaust air, spray air and spray water holes) connector for air and water input and return. A water/air mist cools the head and bur. Dental burs (not part of this 510(k)) according to ISO 1797-1 type 3 could be inserted into the chuck system of the turbine.

The disposable high-speed air turbine dental handpiece is an instrument widely applied in oral therapy. It is composed of interrelated parts, working as a complete set. The disposable high-speed air turbine dental handpiece is an air-driven handpiece which supplied with water and air through the pipe and the coupling of a dental treatment unit. The device contains air and water pipes inside which supply air for driving the turbine assembly rotating and cooling water for work site as well as supply air and water for creating spray. The air-driven turbine assembly provides rotation to

the bur for removing carious material, excess filling material, cavity, and is used for crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.
The handpiece is supplied non-sterile and must be cleaned and sterilized before use.

Indication for use

Disposable high-speed air 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.

Comparison with the predicate device:

Ningbo HPDOVE Dental Instruments Co. Ltd. believes that the Disposable high-speed air turbine handpiece is substantially equivalent to the Codent Technical Industry Co. Ltd. High-speed Handpieces and Accessories (K152146).

The differences noted between the submitted Disposable high-speed air turbine handpiece and the predicate High-Speed Handpieces and Accessories are based on the use. The Disposable High Speed Air Turbine Handpiece, YCX-TOD-PP has the same use as the predicate and used in the same manner. Both the predicate and the submitted Ningbo HPDOVE Dental Instruments Co. Ltd Disposable High-Speed Air Turbine Handpiece, YCX-TOD-PP come non-sterile and must be sterilized before use. Please refer to the following pages for specific difference details.

Comparison to Predicate Devices

Characteristics	**Subject Device**	**Predicate Device**
Name and model	Disposable high-speed air turbine handpiece	High-speed Handpieces and Accessories
Model	YCX-TOD-PP	A4M4
510K Applicant	NINGBO HPDOVE DENTAL INSTRUMENTS CO., LTD.	Codent Technical Industry Co., Ltd.
510(K) Number	Pending	K152146
Regulation Number	CFR872.4200	CFR872.4200
Product Code	EFB	EFB
Classification Name	Air-powered dental handpiece	Air-powered dental handpiece
OTC or Prescription	Prescription Use	Prescription Use
Medical Specialty	Dental	Dental
Indication for Use	Disposable high-speed air 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.
Disposable	Disposable	Re-useable
Principles of Operation	It is a handheld device that connects to a standard turbine connection on a dental operative unit and delivers a mixture of water and air to a treatment site.	It is a handheld device that connects to a standard turbine connection on a dental operative unit and delivers a mixture of water and air to a treatment site.
Operational Mode	Air-powered	Air-powered
Head Type	Standard	Standard
Angle of Shaft	90°	90°
Speed Range in rpms	300,000 rpm to 360,000 rpm	360,000 rpm
Drive Air Pressure	200 kPa - 245 kPa 2.09 kg/cm^2 – 2.5 kg/cm^2	245 kPa- 275 kPa 2.5 kg/cm^2- 2.8 kg/cm^2
Water Spray	Single	Single

Characteristics	Subject Device	Predicate Device
Dental Bur Size	ISO 1797-1 Type3 / Ø1.59~1.60mm	ISO 1797-1 Type3 / Ø1.59~1.60mm
Dimensions(mm)	Length: 142~145 Width: 20.5	Length: 84~117 Width: 19~21
How Supplied	Non-sterile; Subject is sterilized Prior to use.	Non-sterile; Subject is sterilized before each use
Cleaning	Wipe the surface of the device with a clean, soft brush or cotton ball with 75% alcohol	Use the cleaning wire to clean the water spray hole.
Applicable Sterilization	Moist heat - Autoclave sterilization	Moist heat - Autoclave sterilization
Material Composition	Brass, PES, silicon rubber	Stainless steel, Brass, Aluminum, Titanium
Coupling Pin	4-pin(drive air, exhaust air, spray air and spray water holes)	4-pin(drive air, exhaust air, spray air and spray water holes)
Fiber Optics	Without light	Without light
Accessories	Without coupling	Without coupling
Chunk Design	Chuck Tool	Push Button
Bur Extraction Force	22-45 N	22-45 N
Lubrication	Lubricant is not required	Lubricant is required (Codent spray nozzle)
Performance	Complies with ISO 14457 Complies with ISO 9168	Complies with ISO 14457 Complies with ISO 9168
Biocompatibility	Complies with ISO10993-1 & ISO 7405	Complies with ISO10993-1 & ISO 7405

Safety and Performance Data :

To establish substantial equivalence to the identified predicate devices, tests were completed as defined below to the subject devices, Disposable high-speed air turbine handpiece. The results of the testing demonstrate that the device complies with the applicable standards requirements, and the device is substantially equivalent to the predicate device.

Non-Clinical Study:

Performance:

- *ISO 14457 First edition 2012-09-15 Dentistry – Handpieces and motors*
- *ISO 9168 Third edition 2009-07-15 Dentistry – Hose connectors for air-driven dental handpieces*

Biocompatibility:

- *ISO10993-1:2009/AC2010*
- *ISO 10993-5: 2009*
- *ISO 10993-10: 2010*

Sterility:

- *AAMI/ANSI/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 (Sterility)*

- *AAMI/ANSI/ISO 11737-1:2018, Sterilization of health care products -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products.*

- *AAMI/ANSI/ISO 11138-1:2017, Sterilization of health care products -- Biological indicators -- Part 1: General requirements*

- *ANSI AAMI ST79:2017, Comprehensive guide to steam sterilization and sterility assurance in health care facilities*

- *AAMI/ANSI/ISO 14161: 2009, Sterilization of health care products — Biological indicators — Guidance for the selection, use and interpretation of results*

Clinical Study:

- *No clinical studies were performed.*

Package and Shelf Life:

- *The Disposable high-speed air turbine handpiece (YCX-TOD-PP) is not subject to shelf life, as the device does not contain any sterile or degradable elements.*

Conclusion:
The differences between the subject device and predicate device do not raise issues of safety and effectiveness based on the indication for use, technological characteristics, and performance testing. The subject device complies with the same applicable standards as the predicate device.

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, the subject device, Disposable high-speed air turbine handpiece, model YCX-TOD-PP is safe and effective and substantially equivalent to predicate devices as described herein.

END
