Beijing Dongbo Dental Handpiece Co., Ltd. July 11, 2018
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O.box 120-119
Shanghai, 200120 Cn

Re: K172543
Trade/Device Name: High-speed Turbine Handpieces for Single Use
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I
Product Code: EFB
Dated: May 29, 2018
Received: June 7, 2018

Dear Diana Hong:

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 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

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)*
K172543

Device Name
High-speed Turbine Handpieces for Single Use

Indications for Use *(Describe)*
High-speed Turbine Handpieces for Single Use are 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."

510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K172543

1. Date of Preparation: 05/29/2018

2. Sponsor Identification

Beijing Dongbo Dental Handpiece Co., Ltd
Room 201, Building 4, No.9 Anqing Street, Area B of Tianzhu Airport Industrial Zone,
Shunyi District, Beijing, 101318, China

Establishment Registration Number: Not yet registered

Contact Person: Chengfei Yan
Position: Management representative
Tel: +86-10-80479758
Fax: +86-10-80478329
Email: 593893102@qq.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China
Tel: +86(0)21 2281-5850
Fax: +1(0)360 925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: High-speed Turbine Handpieces for Single Use
Common Name: Handpiece, Air-Powered, Dental
Model(s): TBY03-BK, TBY03-BKJ, TBY03-BZJ, TBY03-BZJW, TBY03-BKJW, TBY03-DK, TBY03-DKJ, TBY03-DZJ, TBY03-DZJW, TBY03-DKJW, TBY04-DKJ, TBY04-DZJ

Regulatory Information
Classification Name: Handpiece, Air-Powered, Dental
Classification: I
Product Code: EFB
Regulation Number: 21CFR 872.4200
Review Panel: Dental

Intended Use Statement:
High-speed Turbine Handpieces for Single Use are intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth.

Device Description
The High-speed Turbine Handpieces for Single Use uses compressed air as power source which drives the wind wheel in the head to make drill rotating at very high speed for teeth cutting.

The proposed devices have 12 models. The models difference includes: the size of head, methods of loading the drill, types of coupling, and shape of the shank.

The High-speed Turbine Handpieces for Single Use are single use device. The device is not software driven device, does not include drill.

5. Identification of Predicate Device(s)

Primary Predicate device
510(k) Number: K152146
Product Name: High Speed Handpieces and Accessories

Reference device

510(k) Number: K153411

Product Name: 430 SW Torque High Speed Handpiece Series

6. 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:

- ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process;
- ISO 10993-5: 2009 Biological evaluation of medical device - Part 5: Tests for in vitro cytotoxicity;
- ISO 10993-10: 2010 Biological evaluation of medical device – Part 10: Tests for irritation and skin sensitization;
- ISO 14457: 2012 Dentistry- Handpieces and Motors
- ISO 9168:2009 Dentistry- Hose Connectors for air driven dental handpieces
- ASTM F88/F88M-15: Standard test method for seal strength of flexible barrier materials;
- ISO 11137-2:2013 Sterilization of health care products-Radiation-Part 2: Establishing the sterilization dose;
- Guidance for Industry and FDA Staff- Dental Handpieces – Premarket Notification [510(k)] Submissions

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device	Primary Predicate Device K152146	Reference Device K153411
Classification	I	I	I
Product Code	EFB	EFB	EFB
Regulation Number	872.4200	872.4200	872.4200
Intended Use	High-speed Turbine	High Speed Hnadpieces and	The 430 Torque High-Speed

		Handpieces for Single Use are 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.	Handpieces Series are used by trained dental professionals for a variety of procedures including but not limited to caries and amalgam removal, restorative work and crown preparation.
Operational modes		Air-powered	Air-powered	Air-powered
Material composition		Brass, Aluminum, ABS	Stainless steel, Brass, Aluminum, Titanium	Stainless steel, Aluminum, Optional bead blasted outer surface
Air / Water spray		Water	Water	Water
Water cooling		Yes	Not known	Yes
Fiber optics		Without light	With light/without light	Without light
Coupling		Quick coupling/4-hole coupling	2-hole/4-hole/5-hole/6-hole coupling	Quick coupling
Type of connectors		Hose connection	Hose connection	Hose connection
Speed in rpms		350000 rpm / 380000 rpm	350000 rpm to 400000 rpm	350000 rpm to 450000 rpm
Bur extraction force		＞22N / 22N-45N	22N-45N	Unknown
Single use		Yes	No	No
Sterilization		Radiation / SAL 10^{-6}	Moist heat / SAL 10^{-6}	Moist heat / SAL 10^{-6}
Biocompatibility	Cytotoxicity	No Cytotoxicity	Compliance with ISO 10993 requirements	Compliance with ISO 10993 requirements
	Intracutaneous Reactivity	No Intracutaneous Reactivity		
	Skin Sensitization	No Skin Sensitization		
Performance		Compliance with ISO 14457:2012 and ISO 9168:2009	Compliance with ISO 14457:2012 and ISO 9168:2009	Compliance with ISO 14457:2012

Discussion: The main difference between the proposed device and predicate device is whether a single use device. The proposed device is single used and sterilized by the manufacturer and the sterilization cycle has been validated per ISO 11137-2. The predicate devices are reusable and would be re-sterilized by users. The re-sterilization would be influence or reduce the safety and performance of predicate device, while this would not be occur to the proposed device. Additionally, there are some slight

differences of device design between proposed device and predicate devices, but both the proposed device and predicate devices comply with ISO 14457 and ISO 9168. Therefore, the differences will not affect the substantially equivalency.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.