November 8, 2021

Beijing Dongbo Dental Handpiece Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co.,Ltd
P.O.Box 120-119
Shanghai, 200120
CHINA

Re: K202371
Trade/Device Name: Highspeed Airturbine Handpiece
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EFB
Dated: August 5, 2021
Received: August 10, 2021

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. 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,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K202371

Device Name
Highspeed Airturbine Handpiece

Indications for Use *(Describe)*

This Highspeed Airturbine Handpiece is intended for removal of carious material, cavities and crow preparations, removal of filings, processing of tooth, restoration of surfaces and as a surgical tool for third molar removal procedures
It is designed for use by a trained professional in the field of general dentistry.

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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510(k) Summary

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

The assigned 510(k) Number: K202371

1. Date of Preparation: November 7, 2021

2. Sponsor Identification

Beijing Dongbo Dental Handpiece Co., Ltd.

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)

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Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Highspeed Airturbine Handpiece

Common Name: Handpiece, Air-powered, Dental

Regulatory Information

Classification Name: Dental Handpiece and Accessories

Classification: I;

Product Code: EFB;

Regulation Number: 21CFR 872.4200

Review Panel: Dental

Indication for Use:

This Highspeed Airturbine Handpiece is intended for removal of carious material, cavities and crow preparations, removal of filings, processing of tooth, restoration of surfaces and as a surgical tool for third molar removal procedures

It is designed for use by a trained professional in the field of general dentistry.

Device Description

The Highspeed Airturbine Handpiece is air driven dental handpieces for the use by a trained professional in the field of general dentistry. The devices are air-powered handpieces that are reusable and ergonomically shaped. The devices can be sterilized by the pre-vacuum Autoclave methods. Through the coupling connected to a dental unit, the proposed dental handpiece receive air for functionality of the high speed turbine.

5. Identification of Predicate Device

Predicate device

510(k) Number: K141576

Product Name: Maxima PRO 45L

Reference device

510(k) Number: K172543

Product Name: High-speed Turbine Handpieces for Single Use

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 10993-5: 2009 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10:2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
- ISO 9168:2009 Dentistry - Hose Connectors For Air Driven Dental Handpieces
- ISO 14457:2012 Dentistry - Handpieces And Motors
- ASTM D4169:2016 Standard Practice For Performance Testing Of Shipping Containers And Systems
- Guidance for Industry and FDA Staff- Dental Handpieces- Premarket Notification [510(k)] Submissions
- Cleaning and Sterilization Validation per the FDA Reprocessing Guidance Document

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	Predicate Device K141576	Reference Device K172543	Remark
Product Code	EFB	EFB	EFB	Same
Classification	Class I	Class I	Class I	Same
Regulation Number	21 CFR 872.4200	21 CFR 872.4200	21 CFR 872.4200	Same
Indication for use	This Highspeed Airturbine Handpiece is intended for removal of carious material, cavities and crow preparations, removal of filings, processing of tooth, restoration of surfaces and as a surgical tool for third molar removal procedures It is designed for use by a trained professional in the field of general dentistry.	This air-powered dental handpiece is intended for removal of carious material, cavities and crow preparations, removal of filings, processing of tooth, restoration of surfaces and as a surgical tool for third molar removal procedures It is designed for use by a trained professional in the field of general dentistry.	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.	Same
Principle of operation	Air power	Air power	Air power	Same
Patient-contact material	Brass Aluminum	Round Copper Cr-N/Cr Coating Round Steel Cr Coating Ecobrass	Brass Aluminum ABS	Different
Air/water spray	water	water	Water	Same
Water cooling	Yes	Yes	Yes	Same
Fiber optics	With/without light	With light	Without light	Different
Type of chuck	Push Button	Push Button	Push Button	Same
Light intensity	More than 7000 LUX	Approx. 25,000 LUX	NA	Different
Type of connectors	Hose connection	Hose connection	Hose connection	Same
Speed in rpms	350,000; 380,000; 480,000 rpm	380,000~420,000 rpm	350,000; 380,000rpm	Different
Bur retention force (N cm)	22~45	Up to 24	＞22N/ 22~45N	SE

Head diameter(mm)	12.5, 11, 9.5	12.5	Unknown	Different
Operating Pressure	245Kpa (≈35.53psi)	40psi	245Kpa	Same
Head angle	18 and 45 degree	45 degree	18 and 45 degree	Same
Single use/Reuse	Reuse	Reuse	Single-use	Same
Sterilization	Autoclave sterilization	Gravity steam autoclave	Radiation	Different
Cytotoxicity	Biocompatibility demonstrated by K172543	No Cytotoxicity	No Cytotoxicity	Different
Intracutaneous Reactivity		No Intracutaneous Reactivity	No Intracutaneous Reactivity	
Skin Sensitization		No 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 and ISO 9168:2009	Same

Different- Patient-contact material

The patient-contact materials of the proposed device are different from the predicate devices, but the brass and aluminum of the proposed device is the same as the brass and aluminum of reference device, which is also manufactured by Beijing Dongbo Dental Handpiece Co., Ltd. The biocompatibility test has been conducted on the K172543 and the test result comply with the requirements of ISO 10993. Therefore, the different will not affect the safety and effectiveness of the proposed device

Different- Fiber optics

The fiber optics of the proposed device are different from the predicate device or reference device. The proposed device contains handpieces with and without lighting function. However, the predicate device is handpieces with light and the reference device is handpieces without light. Therefore, the fiber optics (with/without light) will not affect the safety and effectiveness of the proposed device.

Different- Light intensity

The light intensity of the proposed device is different from the predicate device. However, the light intensity of the proposed device meet the requirement of ISO 14457. And the proposed device shall be operated by trained healthcare professions. Therefore, the different will not affect the safety and effectiveness of the proposed device. Therefore, the different will not affect the safety and effectiveness of the proposed device.

Different- Speed in rpms

The speeds of the proposed device are different from the predicate device. The 480,000rpm are out range of the predicate device. The different speeds will be selected by physician per patients' condition.

In addition, the performance test has been conducted on proposed device according to ISO 14457 and the test results meet the acceptable criteria. Therefore, the different will not affect the safety and effectiveness of the proposed device.

Different- Head diameter

The head diameter of the proposed device is different from the predicate device. The 11mm and 9.5mm are out range of the predicate device. However, the difference is just in physical specification and different specification will be selected by physician per patients' condition. Therefore, the different will not affect the safety and effectiveness of the proposed device.

Different- Sterilization

The steam sterilization method of the proposed device are different with the predicate device. However, the sterilization parameters comply with ISO 17665 standard. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Different- Biocompatibility

The patient-contact materials of the Highspeed Airturbine Handpiece are identical device to that of the legally marketed device, High-speed Turbine Handpieces for Single Use, as cleared in K172543, which is also manufactured by Beijing Dongbo Dental Handpiece Co., Ltd. Therefore, the biocompatibility for proposed device is demonstrated by reference device (K172543). The biocompatibility testing for K172543 was evaluated and the tests results complied with ISO 10993 standards. Therefore, the patient-contact materials of the proposed device will not have the adverse effects on patients. Therefore, this difference does not affect the safety and effectiveness of the proposed device.

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.