January 12, 2026

Foshan Topmed Dental Co., Ltd
% Salon Chen
System engineer
IMD Medical & Drug technology service institutions
Room 308, Building 11
No. 23 Jinqu Road, Wanjiang District
Dongguan, Guangdong 523932
China

Re: K251389
Trade/Device Name: High speed air turbine handpiece
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EFB
Dated: May 5, 2025
Received: May 5, 2025

Dear Salon Chen:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, MChE, RAC, CQIA
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251389

Please provide the device trade name(s).

High-speed air turbine handpiece (TM-T1B2、TM-T1M4、TM-T2B2、TM-T2M4、TM-T3B2、TM-T3M4、TM-T4B2、TM-T4M4、TM-T6B2、TM-T6M4)

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K251389 - 510(k) Summary

1. Submitter's Identification:

- Company Name: Foshan Topmed Dental Co., Ltd
- Address: Room 401, Floor 4, Block C, No.7, Gui dan road side section, Luo cun Street, Shi shan Nanhai District, Foshan City
- Phone: +86-757-81803362
- Fax: +86-757-81803362
- Contact Person (Title): Liang Guo chan (General Manager)
- E-mail: TOPMED03 @TOPMEDDENTAL.COM
- Date of Preparation: January 7, 2026

2. Common Name and Classification:

- Device Classification Name: Dental Handpiece and accessories
- Classification Product Code: EFB
- Regulation Number: 21CFR 872.4200
- Class: 1
- Review Panel: Dental
- Device Name: High-speed air turbine handpiece
- Model：TM-T1B2、TM-T1M4、TM-T2B2、TM-T2M4、TM-T3B2、TM-T3M4、TM-T4B2、TM-T4M4、TM-T6B2、TM-T6M4

3. Predicate Device Information:

- 510(k) Number: K170229
- Device Classification Name: Dental
- Sponsor: Guangdong JINME Medical Technology Co., Ltd.
- Classification Product Code: EFB
- Regulation Number: 21CFR 872.4200
- Class: 1
- Review Panel: Dental
- Trade/Proprietary Name: Dental High-speed Turbine Handpiece

- Common Name: Dental Handpiece and Accessories

4. Application Correspondent

- Company Name: IMD Medical & Drug technology service institutions
- Phone: +86-18613190779
- Fax: +86-755-62809168
- Contact Person (Title): Salon Chen (System engineer)
- E-mail：33999439@qq.com
- Address: Room 308, Building 11, No. 23 Jinqu Road, Wanjiang District, Dongguan City, Guangdong Province, China

5. Device Description

High-speed Turbine Air Handpiece is an instrument for drilling, grinding, repairing utilized in dental clinics. It composed of a head, a handle and a connector.

The subject device is intended to be used for dental professional use only.

Lubricant should be used during routine maintenance (e.g. after each patient use and prior to sterilization). The user must buy and use specified lubricant type “PANA SPRAY Plus” manufactured by NAKANISHI INC (cleared in K163483).

6. Indications for Use

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.

7. Comparison to the predicate device

Table 1 General Comparison

Elements of Comparison	Proposed Device	Predicate Device	Judgment
Company Name	Foshan Topmed Dental Co., Ltd	Guangdong JINME Medical Technology Co., Ltd.	/
Device Name	High-speed air turbine handpiece	Dental High-speed Turbine Handpiece	/

Classification Product Code	EFB	EFB	Same
Regulation	21CFR 872.4200	21CFR 872.4200	Same
Classification Name	Dental	Dental	Same
Class	1	1	Same
Prescription or OTC	Prescription Use	Prescription Use	Same
Intended Use	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.	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.	Same

Table 2 Safety factor & Performance Comparison

Safety factor & Performance	Proposed Device	Predicate Device	Judgment
Operational Modes	Air-powered	Air-powered	Same
Water Spray	Single/Triple	Single/Triple	Same
Type of Chunk	Push button	Push button Latch-type chuck	Same
Composition of Main Materials	Stainless Steel, Brass	Stainless Steel, Brass, Titanium	Analysis 1
Bur Extraction Force	The pulling force of the test bar from the mechanical collet shall not be less than 22N	28N	Analysis 2
Operating Pressure	0.20-0.25Mpa	177KPa ~ 301KPa	Analysis 2
Motor Speed	300,000rpm ~ 400,000rpm	300,000rpm ~ 400,000rpm	Same

Sterilization	Steam autoclave method	Steam autoclave method	Same
Compliance Standards	Complied with ISO 10993-5, ISO 10993-10, ISO 10993-23, ISO14457	Complied with ISO 10993-5, ISO 10993-10, ISO14457	Same
Lubricant	The specified lubricant, type "PANA SPRAY Plus" manufactured by NAKANISHI INC (Cleared in K163483), must be used during routine maintenance.	The specified lubricant, type "PANA SPRAY Plus" manufactured by NAKANISHI INC (Cleared in K163483), must be used during routine maintenance.	Same

Review of Differences:

Analysis 1

The main materials of the subject device are different from those in the predicate devices. However, the subject and predicate devices follow ISO 10993-1. The subject device was tested in accordance with the methods outlined in ISO 10993-5:2009, ISO 10993-10:2021, and ISO 10993-23:2021. These tests were selected on characterization of the components in accordance with ISO 10993-1:2018 (Mucosal membrane device, surface contacting, limited contact duration (<24 hours)).

Analysis 2

Although the subject devices are different from the predicate device in Operating Pressure and Bur Extraction Force; the subject devices conform with ISO 14457:2017 *Dentistry - Handpieces and Motors*. The difference in operating pressure and bur extraction force does not affect substantial equivalence between the subject and predicate devices.

8. Discussion of Non-clinical Tests Performed for Determination of Substantial Equivalence:

A series of 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.

1) Basic Safety and Essential Performance

Performance test according to 14457:2017 standard

2) Biocompatibility testing

ISO 10993-1:2018 Biological evaluation of medical devices-Parts 1: Evaluation and testing. ISO 10993-5:2019 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ISO 10993-10:2021 Biological evaluation of medical devices - Parts 10: Tests for skin sensitization

ISO 10993-11:2017 Biological evaluation of medical devices, Part 11: Tests for systemic toxicity ISO 10993-23:2021 Biological evaluation of medical devices-Parts 10: Tests for irritation。

All the test results demonstrate High-speed air turbine handpiece meets the requirements of its **pre-defined acceptance criteria and intended uses, and is substantially equivalent to the predicate device.**

9. Clinical Tests Performed

No clinical test data was used to support the decision of substantial equivalence.

10. Conclusion

The subject devices have all features of the predicate devices. The few differences were evaluated and do not affect the safety and effectiveness of the subject devices compared to the predicate.

Thus, the subject devices are substantially equivalent to the predicate device.