August 23, 2023

Ttbio Corp.
Siow Woon Chyi
Regulatory Affairs Coordinator
2F., No.7, 6th Road Industry Park
Taichung, Taiwan 40755
China

Re: K232243
Trade/Device Name: EVO 700 series high speed handpiece
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EFB
Dated: July 28, 2023
Received: July 28, 2023

Dear Siow Woon Chyi:

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,

FDA Bobak Shirmohammadi -S

For Michael E.Adjodha, M.ChE.,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

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)*
K232243

Device Name
EVO 700 series high speed handpiece

Indications for Use *(Describe)*
The EVO 700 series High Speed Handpieces are designed for removing carious material, reducing hard tooth structure, cavity preparation and finishing tooth preparations/ restorations. The devices are only for dental handpieces treatment and used by a trained person in the field of 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 K232243

EVO 700 series High Speed Handpiece

1. General Information

510(k) Owner	TTBIO CORP. (Registration No.: 3010364969)
Address	2F., No.7, 6th Road, Industry Park, Taichung, Taiwan R.O.C. 40755.
Applicant	Woon Chyi, Siow/ Regulatory Affairs Coordinator
Contact Information	Phone: 886-4-2359 5958 Ext. 731 Email: siowwoonchyi@ttbio.com
Date prepared	July 28, 2023

2. Subject Device

Proprietary Name	EVO 700 series High Speed Handpiece
Regulation Number	21 CFR 872.4200
Regulation Name	Dental handpiece and accessories
Regulatory Class	Class I
Product Code	EFB
Common Name	Handpiece

3. Predicate Device

Proprietary Name	EVO 500 series High Speed Handpiece
Premarket Notification	K141183
Regulation Number	21 CFR 872.4200
Regulation Name	Dental handpiece and accessories
Regulatory Class	Class I
Product Code	EFB
Common Name	Handpiece

4. Device Description

EVO 700 series high speed handpiece, on the scope of 21 CFR 872.4200 Dental handpiece and accessories, product code EFB, is a modification from TTBIO's own legally market predicate device, EVO 500 series high speed handpiece, which is legally marketed on the US dental market per 510(k) clearance, No. K141183.

EVO 700 series high speed handpiece is air-powered dental handpiece that is reusable and ergonomically designed. The handpiece is connected to a dental tubing which delivers driving air, cooling air and water to the cutting bur area. Optional fiber optics deliver light to the cutting area.

This device is to be connected to dental unit and operated by qualified professional (dentist) in the clinic. EVO 700 series high speed handpiece can be connected to couplings that manufactured by TTBIO, KaVo® or NSK®. It is designed in accordance with FDA Recognized Consensus Standards of device-specific guidance document, *ISO 14457:2017 Dentistry - Handpieces and motors* to ensure its safety and effectiveness and follows *ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purpose* regarding to the internal design change control procedure to complete the device design steps.

EVO 700 series high speed handpiece is supplied as non-sterile and can be sterilized by gravity-displacement method, at 132°C for 15 minutes and drying for 30 minutes, and dynamic-air-removal (prevacuum) method, at 134°C for 4 minutes and drying for 15 minutes.

5. Indications for Use:

The EVO 700 series high speed handpieces are designed for removing carious material, reducing hard tooth structure, cavity preparation and finishing tooth preparations/ restorations. The devices are only for dental handpieces treatment and used by a trained person in the field of dentistry .

6. Substantial Equivalence

Table below provides a comparison of the indications for use and key technological characteristics of EVO 700 series with that of the Primary Predicate, EVO 500 series high speed handpiece (K141183).

Model / Particular	Subject Device	Predicate Device	Comparison (Same/ Similar/ Different)
	TTBIO EVO 700 series High speed handpiece	**TTBIO EVO 500 series High speed handpiece**	
Intended use defined under 21 CFR 872.4200	Intended to prepare dental cavities for restorations, such as fillings, and for cleaning teeth.	Intended to prepare dental cavities for restorations, such as fillings, and for cleaning teeth.	Same
Indications for use	The EVO 700 series High Speed Handpieces are designed for removing carious material, reducing hard tooth structure, cavity preparation and	The EVO 500 series High Speed Handpieces are designed for removing carious material, reducing hard tooth structure, cavity preparation and	Same

	finishing tooth preparations/ restorations. The devices are only for dental handpieces treatment and used by a trained person in the field of dentistry.	finishing tooth preparations/ restorations. The devices are only for dental handpieces treatment and used by a trained person in the field of dentistry.	
Principle of operation	The handpiece is connected to a dental tubing which delivers driving air, cooling air and water to the cutting bur area. Optional fiber optics deliver light to the cutting area.	The handpiece is connected to a dental tubing which delivers driving air, cooling air and water to the cutting bur area. Optional fiber optics deliver light to the cutting area.	Same
Device standard	ISO 14457:2017 ISO 9168:2009	ISO 14457:2012 ISO 9168:2009	Similar (Analysis 1)
Rotation speed (rpm)	T: 300,000~360,000 M: 350,000~430,000	T≥300,000 M≥350,000	Similar (Analysis 2)
Chuck system	Push button	Push button	Same
Cooling spray	Multi-spray	Multi-spray	Same
Bur diameter (mm)	Ø1.59~1.60	Ø1.59~1.60	Same
Bur length (mm)	T: 19~25 M: 16~21	T: 19~25 M: 16~21	Same
Drive air pressure (bar)	2.6~3.0	2.6~3.0	Same
Water pressure (bar)	0.8~2.0	0.8~2.0	Same
Chip air pressure (bar)	1.0~3.0	1.0~3.0	Same
Head size (mm)	T: Ø12.2×H13.55 M: Ø10.5×H12.4	T: Ø12.2×H13.55 M: Ø10.5×H12.4	Same
Light system	With or without glass rod	With or without glass rod	Same

Materials of body	Stainless steel	Stainless steel	Same
Light intensity	Approx. 25000 Lux	Approx. 25000 Lux	Same
Bur retention force	Up to 24 N-cm	Up to 24 N-cm	Same

Substantial Equivalence Discussion

Analysis 1:
The dental handpieces are designed according to FDA recognized consensus standard of device-specific guidance document for dental handpiece, ISO 14457:2017. The update of the guidance or standards did not revise or amend the significant characteristics applicable to EVO 700 series and EVO 500 series high speed handpiece. Therefore, this different technological characteristic does not raise different questions of safety and effectiveness.

Analysis 2:
The FDA recognized consensus standard of device-specific guidance document for dental handpiece, ISO 14457:2017 defines requirement on rotation speed for dental handpiece. According to the standard, the free-running speed of the handpieces shall be within ±10% of that specified in the manufacturer's directions for use, and the given range for rotation speed of EVO 700 series high speed handpiece is within the tolerance of the speed stated on directions for use. Therefore, this different technological characteristic does not raise different questions of safety and effectiveness.

Conclusion

According to the discussion above, the indications for use of subject device, EVO 700 series high speed handpiece is same as predicate device, EVO 500 series high speed handpiece, are identical in **the Intended use, Indications for use, Principle of operation, most of the device specifications, and similar, as on the above analysis 1 and 2, in rotation speed (rpm) and complied standards due to the reversion;** and, the other differences in non-significant characteristics are clarified, the substantial equivalent is claimed. Since the differences of the devices do not raise different questions of safety and effectiveness, EVO 700 series is as safe and effective as legally marketed EVO 500 series.

7. Design Control Activities

The risks arisen from the design modifications activities have been identified and evaluated while controlled through a failure modes and effects analysis

(FMEA) that described in FDA-recognized consensus standard, *ISO 14971:2019 Medical devices – Application of risk management to medical devices*. The safety and effectiveness of EVO 700 series high speed handpiece are also verified and validated according to device-specific, FDA-recognized consensus standard, *ISO 14457:2017 Dentistry - Handpieces and motors*. The biocompatibility concerns of new material (PEEK) are confirmed by tests determined in *ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*.

8. Conclusion

Based on the information provided in this premarket notification, the same indications for use with small modifications, EVO 700 series high speed handpiece does not raise different questions of safety and effectiveness and is substantially equivalent to predicate device in terms of safety, effectiveness, and performance.