December 11, 2019

Ttbio Corp.
Shu-Ching Lee
Section Chief
2F, No.7, 6th Road Industry Park
Taichung, 40755
TAIWAN

Re: K190508
Trade/Device Name: EVO 450 series High Speed Handpieces
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental handpiece and accessories
Regulatory Class: Class I, reserved
Product Code: EFB
Dated: November 11, 2019
Received: November 13, 2019

Dear Shu-Ching Lee:

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 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)*

K190508

Device Name

EVO 450 series High speed Handpieces

Indications for Use *(Describe)*

The EVO 450 series is the air-powered dental handpiece which is used by trained dental professionals for removal of carious material, cavities, crown preparations and as a surgical tool for impacted third molar removal and periodontal procedures.

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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TTBIO CORP.
2F, NO.7, 6th ROAD INDUSTRY PARK,
TAICHUNG, TAIWAN, R.O.C. 40755
TEL：886-4-23595958 FAX：886-4-23594196

510(K) SUMMARY-K190508

EVO 450 series High Speed Handpieces

1. Date Prepared: December 10,2019

2. Submitter Information

   510(k) Owner: TTBIO CORP.

   2F, No.7, 6th Road, Industry Park, Taichung, Taiwan, R.O.C. 40755

   Contact Person: Shu-Ching Lee/Section Chief

   Phone: 886-4-23595958/email: jo@ttbio.com

3. Device Name

   Trade Name: EVO 450 series High Speed Handpieces

   Common Name: Dental Handpiece

   Classification Name: Dental Handpiece and Accessories

   (21 CFR 872.4200, Product Code EFB)

4. Predicate Device:

   Maxima PRO2 45L made by Kaltenbach & Voigt GmbH (K141576)

5. Device Description:

   The EVO 450 series High Speed Handpieces are similar to other high-speed dental handpieces currently on the US dental market in design, function, and intended use. The devices are air-powered handpieces that are reusable, ergonomically shaped, and are provided both with and without a fiber optic light system. Several models could be connected to couplings of manufacturers including TTBIO, KaVo, NSK Mach, Sirona, and Star. Others could be connected to hose connectors type 2 or type 3 according to ISO 9168:2009 Dental handpieces-Hose connectors for air driven dental handpieces.

   The EVO 450 series High Speed Handpieces will be supplied with water, air and light through the tube and the coupling of a dental treatment unit. For proper operation, make sure that the supply of cooling air is dry, clean and uncontaminated. Make sure that air is not emitted in the direction of the bur. After each patient use, disinfect the tubing waterlines including the handpiece waterlines by flushing with cleaning water to prevent cross-contamination according to handpiece waterlines disinfection procedure of main dental unit.

Further one there is a nozzle cleaner needle supplied with the EVO 450 series High Speed Handpiece. If spray nozzle is blocked with debris clean the spray nozzle with the nozzle cleaner needle.

6. Intended Use:

The EVO 450 series is the air-powered dental handpiece which is used by trained dental professionals for removal of carious material, cavities, crown preparations and as a surgical tool for impacted third molar removal and periodontal procedures.

7. Substantial Equivalence

The EVO 450 series High Speed Handpieces are the same as predicate device, Air-Powered handpieces, which intended for dentistry treatment and these devices are only for trained persons in the field of dentistry. The proposed devices are essentially identical or similar to the predicate device in terms of the design, principles of operation, technological characteristics and materials. The patient contact materials used are well-known biocompatible, so no new issues of biocompatibility are raised with regard to the proposed devices. Additionally, the proposed devices are complying with FDA recognized standards for High-Speed dental handpieces.

Summary Table of Substantial Equivalence		
Descriptive Information	Proposed Device	Predicate Device
	EVO 450 series	Maxima PRO2 45L (K141576)
Indication for use	The EVO 450 series is the air-powered dental handpiece which is used by trained dental professionals for removal of carious material, cavities, crown preparations and as a surgical tool for impacted third molar removal and periodontal procedures.	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.
Principle of operation	The coupling through the tube connected to a dental unit. The devices receive the air for the turbine to proceed the system used air-powered technique. The cooling water for cutting treatment. And parts of devices have a light system for illumination the operation area.	Through the tube and the coupling connected to a dental unit, the air-powered handpiece receives the air for operating the high speed turbine, the cooling water for cutting treatment through one port and light for illumination the operation area.

Summary Table of Substantial Equivalence		
Descriptive Information	Proposed Device	Predicate Device
	EVO 450 series	Maxima PRO2 45L (K141576)
Water ports	Four	One
Fiber optics	With and without fiber-optic glass rod built-in light system	With built-in light system
Light intensity on input side	N/A	Approx. 25000 Lux
Head Dimensions	Φ10.5×H12.5mm	Φ12.5×H14.6mm
Type of chuck	Push button locking chuck	Identical
Materials of body of the device	Stainless steel	Stainless steel
Bur retention force	Up to 24 N-cm	Identical
Operation pressure	2.0-3.0 bar	2.75±0.1 bar
Speed	360,000~440,000 rpm	380,000~420,000 rpm
Conformance with standards for shank	Ø1.59mm~1.60 mm	Identical
Head angle	45-degree	Identical
Compliance to Standards	ISO 14457:2017 ISO 9168:2009	ISO 14457:2012 ISO 9168:2009
Sterilization Method	Steam Autoclave (Moist Heat)	Steam Autoclave (Moist Heat)
Sterilization Standard	ISO 17665-1:2006	ISO 17665-1:2006

8. Discussion of non-clinical data:

   The functions of EVO 450 series High Speed Handpieces were verified according to ISO14457:2017. Sterilization has been validated in conformance to the FDA recognized consensus standard 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. Cleaning validation testing is performed in accordance with recommended evaluations as listed in AAMI TIR30, AAMI TIR12, and Guidance for Industry and FDA Staff – Processing/Reprocessing Medical Devices in Health Care Settings.

9. Discussion of Clinical Tests Performed:
   N/A

10. Conclusion:
    The EVO 450 series High Speed Handpieces are substantially equivalent to the predicate device. They are same as the predicate device in terms of its intended use, operating principles and functions.