December 4, 2020

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

Re: K201317
Trade/Device Name: TTBIO EVOCLEAN Ultrasonic Scaler
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: Class II
Product Code: ELC
Dated: November 23, 2020
Received: November 27, 2020

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 “Nandu” 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)*

K201317

Device Name

TTBIO EVOCLEAN Ultrasonic Scaler

Indications for Use *(Describe)*

TTBIO EVOCLEAN Ultrasonic Scaler is designed for use during dental cleaning and periodontal debridement of periodontal diseases.

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 FOR K201317

TTBIO EVOCLEAN Ultrasonic Scaler

1. 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

2. Date Prepared: November 23, 2020

3. Device Name

Trade Name: TTBIO EVOCLEAN Ultrasonic Scaler
Common Name: Ultrasonic Scaler
Classification Name: Ultrasonic Scaler (21 CFR 872.4850)
Regulatory Class: II
Product Code: ELC

4. Predicate Device

Primary predicate device: BONART ART-M3II Ultrasonic Scaler UNITS WITH ACCESSORIES made by BONART CO.LTD. (K052028)
No reference devices were used in this submission.

5. Device Description

TTBIO EVOCLEAN Ultrasonic Scaler consists of an ultrasonic generator, a handpiece, a power supply, a foot pedal and other minor accessories. There are two models of TTBIO EVOCLEAN Ultrasonic Scaler, one is EVOCLEAN and the other is EVOCLEAN+. The specifications of these two models are almost the same; the major difference is the connection type, fix and plug in, between the handpiece and main unit. TTBIO EVOCLEAN Ultrasonic Scaler uses ultrasonic energy to generate mechanical micro-vibration of the available inserts to perform the dental procedures defined in its intended use. TTBIO EVOCLEAN Ultrasonic Scaler is a multi-frequency available device which is compatible with 25 KHz or 30 KHz inserts. The system will automatically detect the insert oscillation frequency, need not to operate it manually. The handpiece is connected directly to the device's ultrasonic generator, from which it receives the functional drive signals, search and locate the resonant frequency of the insert, which varies according to the insert in use.

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6. Indications for Use

TTBIO EVOCLEAN Ultrasonic Scaler is designed for use during dental cleaning and periodontal debridement of periodontal diseases.

7. Substantial Equivalence

Substantial Equivalence Comparison Table

	Proposed Device	Primary Predicate Device	Variations
510 (k) Number	K201317	K052028	N/A
Device Trade Name	TTBIO EVOCLEAN Ultrasonic Scaler	BONART ART-M3II Ultrasonic scaler Unit with accessories	Analysis (1)
Regulation Intended Use	"for use during dental cleaning and periodontal (gum) therapy to remove calculus deposits from teeth by application of an ultrasonic vibrating scaler tip to the teeth."	"for use during dental cleaning and periodontal (gum) therapy to remove calculus deposits from teeth by application of an ultrasonic vibrating scaler tip to the teeth."	Identical
Indications for use	The device is designed for use during dental cleaning and periodontal debridement of periodontal diseases.	Ultrasonic procedures: -Removal of calculus and plaque during dental prophylaxis. -General supra and sub-gingival scaling applications. -Periodontal debridement for all types of periodontal diseases. -Endodontic procedures.	Similar
contraindications	-Do not use TTBIO EVOCLEAN Ultrasonic Scaler for amalgam restorative dental procedures. -Do not use this device if the patient or operator is wearing a pacemaker.	-Do not use the BONART ART-M3II for amalgam restorative dental procedures. -Do not use the BONART ART-M3II if the patient or operator is wearing a pacemaker.	Identical
Prescription/ over-the-counter use	Prescription use	Prescription use	Identical
Components	-Main Unit -Handpiece -Foot pedal -Power supply, AC power cord -Water supply line with quick disconnect -Directions For Use	-Main Unit -Handpiece -Foot control / Foot switch -AC power cord set -PU water tubing, quick disconnect -User Manual -Inserts	Analysis (1)
Direct patient-contacting Material	No	Insert: Plastic, Metal	Analysis (1)

Revised date: November 23, 2020

	Proposed Device	Primary Predicate Device	Variations
User Contact Material	Case：ABS and PC Others：PA, TPU and PVC	Case：Ferrous cover Others：Unknown	Analysis (2)
Treatment	Ultrasonic Scaling	Ultrasonic Scaling	Identical
Mechanism of treatment	application of an ultrasonic vibrating scaler tip to the teeth	application of an ultrasonic vibrating scaler tip to the teeth	Identical
Input Power	100-240 VAC , 50/60 Hz	115V±5% ~50/60Hz 230V±5% ~50/60Hz	Analysis (3)
Power (Max)	60 W	92 VA	Analysis (3)
Scaler tip frequency	25 / 30 KHz	25 / 30 KHz	Identical
Water supply pressure	25 to 40 psi (172 to 275 kPa)	25 to 60 psi (172~414KPa)	Similar
Weight	4.4 lbs (2kg)	3.5kg (include handpiece)	Analysis (4)
Dimensions	15cm(D)x12.5cm(W)x 8.5cm(H) Handpiece Cable: 250cm Foot Pedal Cable: 250cm	26cm(L)x 18.5cm(W)/x 7cm(H) Handpiece Cable: 250cm Footswitch Cable: 250cm	Analysis (4)
Operating Mode	Intermittent, Boost, Purge and Cruise	Continuous Operation	Analysis (5)
Flow rate adjustment	Mechanical regulator	Mechanical regulator	Identical
Housing	Stand alone device	Stand alone device	Identical

TTBIO EVOCLEAN ultrasonic scaler is same with primary predicate device which intended for cleaning and periodontal therapy, and the device is only for operation by a trained professional in the field of general dentistry. The proposed device is essentially identical or similar to the primary predicate device in indications for use, principles of operation, energy source and technological characteristics. The minor differences are:

Analysis (1) The insert is not included in proposed device as its accessories.

Analysis (2) The material of proposed device is different from primary predicate device. However, the biocompatibility for proposed device has been evaluated, so no new issue of biocompatibility is raised with regard to the proposed devices.

Analysis (3) The electrical safety for proposed device has been tested and the test result is acceptable. This difference does not affect substantially equivalence.

Analysis (4) The proposed device has lighter weight and smaller size, these differences are negligible.

Analysis (5) The software validation report was provided to ensure these operating modes fulfills its intended purpose.

Based on performance testing methods and results, there is no significant difference in accordance with international standard ISO 18397:2016 (Dentistry – Powered scaler).

8. Non-clinical Testing:

The functions of TTBIO EVOCLEAN Ultrasonic Scaler were verified according to ISO18397:2016.

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.

The biocompatibility evaluation for TTBIO EVOCLEAN Ultrasonic Scaler was conducted in accordance with Guidance for Industry and FDA Staff – Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”.

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”.

EMC and Electrical safety testing comply with IEC 60601-1-2:2014 and ANSI/AAMI ES60601-1:2005/(R)2012 & A1:2012.

9. Clinical Testing:

No clinical testing was conducted for this submission.

10. Conclusion:

TTBIO EVOCLEAN Ultrasonic Scaler, model EVOCLEAN and model EVOCLEAN+, is substantially equivalent to the primary predicate device. They are same as the primary predicate device in terms of its intended use, operating principles and functions.