February 2, 2022

TTBIO CORP.
Shu-Hui Lin
Assistant Engineering
2F, No.7, 6th Road, Industry Park
Taichung, TAIWAN 40755
Taiwan

Re: K210832
Trade/Device Name: EVOCLEAN CLEANsert Ultrasonic Insert
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: Class II
Product Code: ELC
Dated: December 30, 2021
Received: January 5, 2022

Dear Shu-Hui Lin:

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 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)*
K210832

Device Name
EVOCLEAN CLEANsert Ultrasonic insert

Indications for Use *(Describe)*

To be used by dental professionals for dental cleaning and periodontal(gum) therapy to remove calculus from the teeth.

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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TEL : 886-4-23595958 FAX : 886-4-23594196

510(K) SUMMARY – K210832

EVOCLEAN CLEANsert Ultrasonic Insert

1. **Submitter Information**

510(k) Owner: TTBIO CORP.
2F, No.7, 6th Road, Industry Park, Taichung, Taiwan, R.O.C. 40755
Contact Person: Helen Hsu/Assistant Engineering
Phone: 886-4-23595958
Email: helen@ttbio.com

2. **Date Prepared:** Jan 28, 2022

3. **Device Name**

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

4. **Predicate Device**

Satin Swivel Ultrasonic Insert made by Hu-Friedy Mfg. Co., Inc. (K012060)

5. **Device Description**

EVOCLEAN CLEANsert Ultrasonic Insert is used with EVOCLEAN Ultrasonic Scaler that was cleared under K201317. It is used by dental professionals for dental cleaning and periodontal (gum) therapy to remove calculus from the teeth. EVOCLEAN CLEANsert Ultrasonic Inserts are available in three models (ELITE IF-50 Universal Slim, PRO IF-50 Universal Slim and CLASSIC P-10 Universal). Each model has two oscillating frequencies (25KHz and 30KHz), three different grip sleeves and two water supply methods (internal/external). EVOCLEAN CLEANsert Ultrasonic Insert consists of a Tip, a Magnetostrictive stack, an Inner O-ring, a Grip sleeve and an Outer O-ring. CLASSIC P-10 Universal has an external water tube.

6. **Indications for Use**

To be used by dental professionals for dental cleaning and periodontal(gum) therapy to remove calculus from the teeth.

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7. Substantial Equivalence

	Subject Device	Predicate Device	Variations
510 (k) Number	K210832	K012060	N/A
Device Trade Name	EVOCLEAN CLEANsert Ultrasonic Insert	Hu-Friedy Satin Swivel Ultrasonic Insert	
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	To be used by dental professionals for dental cleaning and periodontal(gum) therapy to remove calculus from the teeth.	To be used by dental professionals for dental cleaning and periodontal(gum) therapy to remove calculus from the teeth.	Identical
Prescription/ over-the-counter use	Prescription use	Prescription use	Identical
Principle of Operating	Inserts interact with magnetostrictive ultrasonic handpiece and unit and operate in the range of 25,000Hz / 30,000Hz.	Inserts interact with magnetostrictive ultrasonic handpiece and unit and operate in the range of 25,000Hz / 30,000Hz.	Identical
Material	Scaler Tip: Metal Grip Sleeve: Silicone, Resin, Metal Magnetostrictive stack: Nickel	---	Analysis 1
Biocompatibility	ISO 10993-5 ISO 10993-10	---	
Flow fluid pathway	Internal / External	Internal	Analysis 2

	Subject Device	Predicate Device	Variations
Sterilization Status	Provided non-sterile	Provided non-sterile	Identical
Sterilization	Gravity Steam sterilize for 30 minutes at 250°F/121°C.	---	Analysis 3
Drying	Recommend 30 minutes dry time after sterilization cycle.	---	
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
Performance Testing	Supply of cooling liquid Extraction force Insertion force Frequency and Amplitude	---	Identical

Analysis 1: materials contact with patients and users have passed the biocompatibility test.

Analysis 2: supply of cooling liquid, extraction force, insertion force, frequency and amplitude have passed the performance test which concludes these differences do not raise any safety or performance concerns.

Analysis 3: the parameters of sterilization and drying have been validated through moist heat sterilization validation test which according to ISO 17665-1.

EVOCLEAN CLEANsert Ultrasonic Insert is the same as the predicate device which is to be used by dental professionals for dental cleaning and periodontal(gum) therapy to remove calculus from the teeth. The proposed device is the same as the predicate device in indications for use, materials and technological characteristics. We performed applicable tests to support biocompatibility, including Cytotoxicity, Sensitization and Irritation. The differences do not raise additional questions regarding safety and effectiveness.

8. Non-clinical Testing

The functions of EVOCLEAN CLEANsert Ultrasonic Insert were verified according to ISO18397:2016.

Cleaning and sterilization validation testing is performed in accordance with recommended evaluations as listed in AAMI TIR30 and Guidance for Industry and FDA Reprocessing Guidance titled: “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling – Guidance for Industry and Food and Drug Administration Staff.”

The biocompatibility evaluation for EVOCLEAN CLEANsert Ultraonic Insert 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”. The insert passed testing for cytotoxicity, sensitization, irritation testing, acute toxicity and pyrogenicity.

9. Clinical Testing

No clinical testing was conducted for this submission.

10. Conclusion

The differences between the proposed subject device and the predicates do not raise any different questions safety or effectiveness. We can conclude that EVOCLEAN CLEANsert Ultrasonic Insert can be considered substantially equivalent to the predicate.