July 1, 2024

Dent4You AG
Tricia Cregger
Global Regulatory Affairs Manager
Bahnhofstrasse 2
Heerbrugg, 9435
SWITZERLAND

Re: K240801
Trade/Device Name: BioSonic US200 Ultrasonic Scaler (60034537)
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: Class II
Product Code: ELC
Dated: March 22, 2024
Received: March 25, 2024

Dear Tricia Cregger:

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.

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,

Michael E. Adjodha -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240801

Device Name

BioSonic US200 Ultrasonic Scaler (60034537)

Indications for Use *(Describe)*

Ultrasonic Applications for:
- All sub-gingival and supra-gingival scaling and routine prophylaxis procedures.
- Periodontal therapy

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K240801

510(k) Summary

Prepared on: 2024-06-26

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Dent4You AG
Applicant Address	Bahnhofstrasse 2 Heerbrugg 9435 Switzerland
Applicant Contact Telephone	330-916-8904
Applicant Contact	Dr. Tricia Cregger
Applicant Contact Email	tricia.cregger@coltene.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	BioSonic US200 Ultrasonic Scaler (60034537)
Common Name	Ultrasonic scaler
Classification Name	Scaler, Ultrasonic
Regulation Number	872.4850
Product Code(s)	ELC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K983727	BioSonic Ultrasonic Scaler System	ELC

Device Description Summary

21 CFR 807.92(a)(4)

The BioSonic US200 Ultrasonic Scaler is an ultrasonic scaling unit that is used in sub-gingival and supra-gingival scaling and routing prophylaxis procedures, and periodontal therapy. The BioSonic US200 Ultrasonic Scaler includes the main unit, handpiece, footswitch, removable sheath, and a selection of scaler inserts. This device generates high frequency waves that cause the tip of the scaler insert to vibrate at 25kHz or 30kHz depending on the scaler insert used.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Ultrasonic Applications for:
- All sub-gingival and supra-gingival scaling and routine prophylaxis procedures.
- Periodontal therapy

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the BioSonic US200 Ultrasonic Scaler are identical to the indicatrions for use of the predicate device, the BioSonic Ultrasonic Scaler System.

Technological Comparison

21 CFR 807.92(a)(6)

The BioSonic US200 Ultrasonic Scaler (subject device) and the BioSonic Ultrasonic Scaler System are both ultrasonic scalers for sub-gingival and supra-gingival scaling and routine prophylaxis procedures and periodontal therapy. The indications for use are identical and the technological characteristics are substantially equivalent with only minor differences, including the mechanism to change from NORMAL to Turbo Mode, the automatic frequency detection of the scaler insert, and the removable autoclavable sheath. These minor differences do not constitute a new intended use or raise different questions of safety and effectiveness compared with the predicate

device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Performance testing was conducted to verify that the proposed BioSonic US200 Ultrasonic Scaler meets the requirements of IEC 60601-1 and IEC 60601-1-2. Software verification and validation of the device were conducted in accordance with the FDA Guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" Performance Testing – Bench, of this Premarket Submission, contains detailed information regarding the proposed BioSonic US200 Ultrasonic Scaler including testing protocols, test objectives, test articles, test methods and procedures, and acceptance criteria.
Non-clinical tests performed to establish substantial equivalence to the identified predicate device including frequency testing, power testing, tip displacement testing, insert extraction testing, life testing and, and materials compatibility testing with cleaning and disinfecting agents.

Not Applicable

Based on the non-clinical performance data the proposed BioSonic US200 Ultrasonic Scaler is as safe, as effective, and performs as well as or better than the predicate device BioSonic Ultrasonic Scaler system (K983727, 21 CFR 872.4850, product code ELC.)