October 27, 2023

ProEdge Dental Products, Inc.
℅ Ian Trump
Principal Scientist
Exponent, Inc.
980 9th Street, 16th Floor
Sacramento, California 95814

Re: K232393
Trade/Device Name: BluTube® Dental Unit Water Purification Cartridge (BluTube®)
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit And Accessories
Regulatory Class: Class I, reserved
Product Code: QYJ, EIA
Dated: August 9, 2023
Received: August 9, 2023

Dear Ian Trump:

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 Adjodha, MChE, RAC, CQIA
Assistant Director
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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)*
K232393

Device Name
BluTube® Dental Unit Water Purification Cartridge

Indications for Use *(Describe)*
The BluTube®Dental Unit Water Purification Cartridge is for use on dental unit water lines attached to the dynamic dental instruments, i.e., high-speed handpiece, three-way airwater syringe and ultrasonic scaler. This cartridge in conjunction with currently recommended practices regarding sterilization and flushing of dental instruments reduces bacteria from the water supplied to the instruments to less than 200 CFU/mL, a level that will meet or exceed the current American Dental Association (ADA) recommendations for water quality.

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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5 510(k) Summary K232393

Traditional 510(k) Summary for BluTube® Dental Unit Water Purification Cartridge

5.1 Submitter

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Date Prepared: February 18th, 2020

5.2 Primary Contact

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5.3 Device Name

Name of Device: BluTube® Dental Unit Water Purification Cartridge
Common or Usual Name: Dental Unit Waterline Purification Cartridge
Classification Name: Dental operative unit accessory (21 CFR 872.6640)
Regulatory Class: Class I
Product Code: QYJ, EIA

5.4 Predicates

Primary Predicate: DentaPure® DP90 Cartridge; DentaPure® DP365 Cartridge (K992893)
Common or Usual Name: Dental Unit Waterline Treatment Cartridge and Dental Unit Purification Cartridge
Classification Name: Dental operative unit accessory (21 CFR 872.6640)
Regulatory Class: Class I
Product Code: EIA

Additional Predicate: DentaPure® DP40 Cartridge (K992868)
Common or Usual Name: Dental Unit Waterline Purification Cartridge
Classification Name: Dental operative unit accessory (21 CFR 872.6640)
Regulatory Class: Class I

Product Code: EIA

5.5 Device Description

BluTube® is a dental unit waterline purification cartridge intended for use at dental offices to reduce microbial bioburden in dental unit waterlines (DUWLs). BluTube® is placed in-line with the pick-up tube of the water supply bottle of a dental operative unit (DOU). Once installed, water flows into the device and through the iodinated resin chamber. Bacterial populations in the treated water are reduced through the antimicrobial action of iodine, which is released from the iodinated resin and into the treated water. Treated water expelled from BluTube® can be used as an irrigant/coolant for nonsurgical dental procedures and is appropriate for use in dental instruments like air/water syringes or high-speed handpieces.

ProEdge intends to market two models of the BluTube® device. The two BluTube® models are identical in terms of design and performance characteristics. The only difference is in the labeling and respective replacement schedules to fit requirements of dental offices. The two models and respective replacement schedules are described in Table 5-1 below. The purpose of providing two models with different replacement schedules is to give dental offices the option of choosing the frequency of change-out schedule for the DUWL treatment products.

Table 5-1: BluTube Models and Replacement Schedules

Model #	If Water Usage Records are Kept	If No Water Usage Records are Kept	If Iodine Concentration is Monitored
BT180	120 liters (L)	6 months (180 days)	Change when iodine output falls to less than 0.5 ppm
BT90	60 L	3 months (90 days)	

5.6 Principal of Operation

Bacterial populations in the treated water are reduced through the antimicrobial action of iodine from the iodinated resin present in the device. The use pattern for the iodinated resin as present in BluTube® is consistent with the United States Environmental Production Agency (USEPA)-registered label for the iodinated resin. The mechanism of action for BluTube® is the same as its cited predicates, which also employ iodinated resin for this purpose.

5.7 Indications for Use

BluTube® is intended for use at dental offices and is compatible with DOUs utilizing bottle-type water supply systems with water pressures ≤ 45 pounds per square inch (psi). BluTube® is not intended for the treatment of water for dental surgery applications where the utilization of sterile water is required. The following Indications for Use statement is proposed for BluTube®:

"The BluTube® Dental Unit Water Purification Cartridge is for use on dental unit water lines attached to the dynamic dental instruments, i.e., high-speed handpiece, three-way air/water syringe and ultrasonic scaler. This cartridge in conjunction with currently recommended practices regarding sterilization and flushing of dental instruments reduces bacteria from the water supplied to the instruments to less than 200 CFU/mL, a level that will meet or exceed the current American Dental Association (ADA) recommendations for water quality."

The Indications for Use statement for BluTube® is not identical to the predicate devices, with the main difference being citation of the revised ADA microbiological water quality recommendation. These differences do not alter the intended therapeutic use of the device and do not raise any new questions of safety or effectiveness relative to the predicate devices.

5.8 Description of Substantial Equivalence

5.8.1 Technological Characteristics

BluTube® has similar physical and technical characteristics to the predicate devices, as illustrated in Table 5-2 below.

Table 5-2: Summary Substantial Equivalence Comparison

Parameter	BluTube® Cartridge	DentaPure® DP365 (Primary Predicate)	DentaPure® DP40
510(k)#	K232393	K992893	K992868
Product Code	QYJ, EIA	EIA	EIA
Device Class	Class I	Class I	Class I
Regulation Number	21 CFR 872.6640	21 CFR 872.6640	21 CFR 872.6640
Indication	The BluTube® Dental Unit Water Purification Cartridge is for use on dental unit water lines attached to the dynamic dental instruments, i.e., high-speed handpiece, three-way air/water syringe and ultrasonic scaler. This cartridge in conjunction with currently recommended practices regarding sterilization and flushing of dental instruments reduces bacteria from the water supplied to the instruments to less than 200 CFU/mL, a level that will meet or exceed the current American Dental Association (ADA) recommendations for water quality.	The DentaPure® DP90 and DP365 Cartridge is for use on dental unit water lines attached to the dynamic dental instruments, i.e., high-speed handpiece, three-way air/water syringe and ultrasonic scaler. This cartridge in conjunction with currently recommended practices regarding sterilization and flushing of dental instruments reduces bacteria from the water supplied through the instruments to a level that will meet or exceed the current ADA recommendations for water quality having a maximum of 200 cfu/ml.	The DentaPure® DP40 Cartridge is for use on dental unit water lines attached to the dynamic dental instruments, i.e., high-speed handpiece, three-way air/water syringe and ultrasonic scaler. This cartridge in conjunction with currently recommended practices regarding sterilization and flushing of dental instruments reduces bacteria from the water supplied through the instruments to a level that will meet or exceed the current ADA recommendations for water quality having a maximum of 200 cfu/ml.
Installation Location	Connected to pickup tube of bottle water system	DP365M is connected to municipal water supply junction; model DP365B is connected to pickup tube	Connected to pickup tube of bottle water system

Parameter	BluTube® Cartridge	DentaPure® DP365 (Primary Predicate)	DentaPure® DP40
Replacement Schedule	If iodine is monitored, when iodine output falls to less than 0.5 ppm. If water usage records kept, when 60 L (BT90) or 120 L (BT180) are treated. If water usage records are not kept, at 90 (BT90) or 180 (BT180) calendar days	If iodine is monitored, when iodine output falls to less than 0.5 ppm. If water usage records kept, when 240 L are treated. If water usage records are not kept, at 365 calendar days	If iodine is monitored, when iodine output falls to less than 0.5 ppm. If water usage records kept, when 40 L are treated. If water usage records are not kept, at 60 calendar days
Maximum Pressure Rating (psi)	45	45	45
Antimicrobial Active	Iodine (CAS No. 7553-56-2)	Iodine (CAS No. 7553-56-2)	Iodine (CAS No. 7553-56-2)
Resin Composition	47.5% iodine bound to anion exchange resin	46% iodine bound to anion exchange resin	46% iodine bound to anion exchange resin

5.8.2 Performance Testing

The following performance data were provided in support of the substantial equivalence determination.

- Maximum Iodine Concentration: Under simulated use conditions (≥ 120 L of water treated), the maximum concentration of iodine in water treated by BluTube® was substantially equivalent to the maximum concentration of iodine in water treated by Dentapure DP365B (K992893).

- Minimum Iodine Concentration: Under simulated use conditions (≥ 120 L of water treated), both BluTube® and the Dentapure DP365B (K992893) predicate maintained iodine concentrations ≥ 0.5 ppm.

- Antimicrobial Efficacy: Under simulated use conditions (≥ 120 L of water treated), bacterial concentrations in DUWL water treated by BluTube® and the Dentapure DP365B predicate (K992893) were ≤ 200 CFU/mL.

5.8.3 Biocompatibility

Iodine released from the iodinated resin is the only direct patient-contacting component of BluTube®. The maximum concentration of iodine in BluTube®-treated DUWL water was substantially equivalent to the maximum concentration of iodine in water treated with the predicate devices.

The maximum concentration of iodine in BluTube®-treated DUWL water, as well as the materials used to manufacture the BluTube device that could indirectly contact patients, were evaluated according to ISO 10993-1:2018, ISO 7405:2018, and FDA's 2020 guidance: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management

process". The evaluation indicated no new risks to biocompatibility have been found for the BluTube® device.

The manufacturing processes and the packaging materials were also evaluated, as these directly contact the device, and no biocompatibility risks were identified due to manufacturing process materials or device-contacting packaging materials.

5.8.4 Substantial Equivalent Conclusion

BluTube® and its cited predicates (K992893 and K992868) were compared based on their intended use, indications, technological characteristics, principle of operation, and performance in bench testing intended to evaluate safety and effectiveness. On the basis of these comparisons, BluTube® is determined to be substantially equivalent to the cited predicates.