August 8, 2024

Odne AG
Mark Bispinghoff
COO
Ringstrasse 14
Dübendorf, ZH 8600
Switzerland

Re: K233844
Trade/Device Name: OdneClean
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: Class II
Product Code: ELC
Dated: July 17, 2024
Received: July 17, 2024

Dear Mark Bispinghoff:

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,

FDA

Bobak
Shirmohammadi -S

For 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)*

K233844

Device Name

OdneClean

Indications for Use *(Describe)*

OdneClean is intended to prepare, clean, and irrigate teeth indicated for root canal 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) #: K233844

510(k) Summary

Prepared on: 2024-08-08

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Odne AG
Applicant Address	Ringstrasse 14 Dübendorf ZH 8600 Switzerland
Applicant Contact Telephone	+41445896802
Applicant Contact	Dr. Mark Bispinghoff
Applicant Contact Email	mark.bispinghoff@odne.co

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	OdneClean
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
K143448	Sonendo Gentlewave System	ELC
K093000	EMS Piezon Master 700	ELC
K211721	PS System	NYL

Device Description Summary

21 CFR 807.92(a)(4)

OdneClean is a dental device for the preparation, cleaning, and irrigation of root canals during endodontic procedures. It achieves this by the creation of hydraulic cavitation inside the root canal. It consists of a console (control unit), an irrigation fluid reservoir (saline solution bag or bottle), and a handpiece that is equipped with single-use OdneClean tips.

OdneClean delivers a stream of pressurized irrigation fluid (0.9 % NaCl) into the root canal. Upon leaving the narrow nozzle of the tip, it creates hydraulic cavitation inside the fluid stream, which enables the removal of organic matter from the root canal.

OdneClean features a user interface on its console and an on/off button on the handpiece. It provides automatic priming and disinfection programs to prepare the device for use and disinfect the internal fluid path after use. A waste container collects the fluid generated during priming and disinfection.

OdneClean is used after a conventional access cavity preparation, glide path preparation, determination of the working length, and minimal shaping of the root canal. Following OdneClean treatment, root canals are to be disinfected and obturated using standard procedures.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

OdneClean is intended to prepare, clean, and irrigate teeth indicated for root canal therapy.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject device has identical indications for use in comparison to the predicate devices.

Technological Comparison 21 CFR 807.92(a)(6)

OdneClean has the same type of use, target users, mechanism of action, infection control of the console, materials, flowrate, and power source as the predicate devices. It further shares the same treatment site, and applied part classification with the primary predicate device, Sonendo Gentlewave System (K143448). The irrigation fluid, 0.9% NaCl, is the same as in the additional predicate device, EMS Piezon Master 700 (K093000).

OdneClean has some minor differences in technological characteristics from those of the predicate devices. These differences are only minor, such as handpiece button control, infection control of the handpiece, electrical safety classification, ingress protection, weight, and operating conditions, and were determined to not affect the substantial equivalence of the subject device.

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

For OdneClean, the following non-clinical tests were performed to support substantial equivalence of the subject device:

Benchtop performance testing
OdneClean was subjected to verification and validation testing for system pressure, temperature, cavitation, root canal cleaning, apical pressure, flow rate, chemical resistance, and resistance to reprocessing. Testing was conducted using internal methods. The results of these tests demonstrate compliance with the requirements of the following standards and guidance:
• IEC 80601-2-60:2019 (FDA recognition #4-262) "Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment"
• ISO 14457:2017 (FDA recognition #4-276) "Dentistry - Handpieces and motors"
• FDA guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions", issued December 20, 2019.
All tests showed the expected results and met the pre-established acceptance criteria. The performance test results support the substantial equivalence of the subject to the predicate device.

Electromagnetic compatibility & Electrical, mechanical, and thermal safety
Electromagnetic compatibility and electrical safety testing of OdneClean demonstrates compliance with the requirements of the following standards and guidance:
• IEC 60601-1-2:2014 (FDA recognition #19-36) "Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests"
• IEC 60601-1:2020 (FDA recognition #19-49) "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance"
• IEC 80601-2-60:2019 (FDA recognition #4-262) "Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment"
• FDA guidance "Electromagnetic Compatibility (EMC) of Medical Devices", issued June 6, 2022
• FDA guidance "Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment – Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program", issued September 25, 2020

Biocompatibility
Biocompatibility evaluation and testing of OdneClean demonstrates compliance with the requirements of the following standards and guidance:
• ISO 7405:2018 (FDA recognition #4-261) "Dentistry - Evaluation of biocompatibility of medical devices used in dentistry"
• ANSI ADA 41-2020 (FDA recognition #4-295) "Evaluation of Biocompatibility of Medical Devices Used in Dentistry"
• ISO 10993-1:2018 (FDA recognition #2-258) "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"
• ISO 10993-5:2009 (FDA recognition #2-245) "Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity"
• ISO 10993-10:2021 (FDA recognition #2-296) "Biological evaluation of medical devices - Part 10: Tests for skin sensitization"
• ISO 10993-11:2017 (FDA recognition #2-255) "Biological evaluation of medical devices - Part 11: Tests for systemic toxicity"
• ISO 10993-23:2021 (FDA recognition #2-291) "Biological evaluation of medical devices - Part 23: Tests for irritation"
• FDA guidance "Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", issued September 8, 2023
Toxicological risk assessment of the materials of construction together with biological testing (cytotoxicity, sensitization, irritation, acute systemic toxicity, and material-mediated pyrogenicity) concluded that OdneClean is biocompatible and supports substantial

equivalence.

Reprocessing Validation
The validation of OdneClean's cleaning and intermediate-level disinfection instructions for its external surfaces and its fluid path demonstrates compliance with the requirements of the following standards and guidance:
• USP 1227 "Validation of Microbial Recovery from Pharmacopeial Articles"
• AAMI TIR12:2020 "Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers"
• AAMI TIR30:2011 "A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices"
• ANSI AAMI ISO 11737-1:2018 (FDA recognition #14-577) "Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on product"
• ANSI AAMI ST 98:2022 "Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices"
• ASTM F3208-20 (FDA recognition #8-549) "Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices"
• ASTM F3293-18 (FDA recognition #14-517) " Standard Guide for Application of Test Soils for the Validation of Cleaning Methods for Reusable Medical Devices"
• FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling", issued March 17, 2015

Software
OdneClean's software validation demonstrates compliance with the requirements of the following standard:
• IEC 62304:2014 (FDA recognition #13-79) "Medical device software - Software life cycle processes"

OdneClean has passed all benchtop performance tests and meets their pre-established acceptance criteria. The determined performance parameters are compatible with the requirements for the intended use and support the substantial equivalence of the subject to the predicate device.