March 20, 2026

Dental Imaging Technologies Corporation
℅ Peter Schmidt
Sr. Regulatory Affairs Specialist
450 Commerce Dr.
QUAKERTOWN, PA 18951

Re: K253864
Trade/Device Name: NOMAD Pro 3
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: Class II
Product Code: EHD
Dated: February 17, 2026
Received: February 17, 2026

Dear Peter Schmidt:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253864

Please provide the device trade name(s).

NOMAD Pro 3

Please provide your Indications for Use below.

The NOMAD Pro 3 Handheld X-ray System is indicated for use only by a trained and qualified dentist or dental technician for both adult and pediatric subjects as an extraoral diagnostic dental X-ray source to produce X-ray images using intraoral image receptors.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K253864

510(k) Summary

Prepared on: 2026-03-20

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Dental Imaging Technologies Corporation
Applicant Address	450 Commerce Drive Quakertown PA 18951 United States
Applicant Contact Telephone	516-375-5332
Applicant Contact	Mr. Peter Schmidt
Applicant Contact Email	regulatory2@dexis.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	NOMAD Pro 3
Common Name	Extraoral Source X-Ray System
Classification Name	Extraoral Source X-Ray System
Regulation Number	872.1800
Product Code(s)	EHD

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K173319	KaVo NOMAD Pro 2 Handheld X-ray System	EHD

Device Description Summary

21 CFR 807.92(a)(4)

NOMAD Pro 3 Handheld X-ray System is a battery-operated, portable dental X-ray source designed for handheld operation. It is designed to produce diagnostic quality X-rays images utilizing either film or digital imaging techniques. The NOMAD Pro 3 Handheld X-ray System is designed for use in a dental office. It can also be used in other similar environments (orthodontic office, general practitioner's office, hospital ward, etc.) where appropriate safeguards are implemented. The device uses a rechargeable battery to allow for the use of the NOMAD Pro 3 Handheld X-ray System where transportation or use of other x-ray devices might be prohibitive due to the other device's size and/or lack of mobility.

System Description and Overview: The NOMAD Pro 3 Handheld X-ray System is an X-ray device with a DC generator. The handheld device features a main unit (tube head), rechargeable battery (handset), charger, and charger AC/DC power supply. The power is supplied by a rechargeable Lithium-ion battery core pack built into a handset. This facilitates portability of the device. A beam-limiting cone is incorporated within the device. Internal and external shielding provide sufficient radiation protection to allow the clinician to remain in the operatory with the patient.

To make the system as simple as possible for the operator, NOMAD Pro 3 Handheld X-ray System uses a fixed tube voltage of 65kV and a fixed tube current of 2.5mA. The only operator-adjustable parameter is the exposure time. This adjustment can be quickly accomplished through the user-friendly control panel.

The battery core pack consists of standard production, high discharge, cylindrical, Lithium-ion cells. The vendor builds the cells into custom, potted enclosure which also contains control and safety circuitry in the form of a semi-custom Battery Management Unit (BMU). The internal potting provides protection against liquid ingress and further inhibits flame propagation in the event of a single cell failure. The BMU provides charge control, discharge control, battery capacity management, safety control and communication. The electrical interface includes a two-wire serial interface which may be used to obtain status of the battery core pack.

Control buttons, display, and a trigger provide the primary operator interface. Exposure settings can be selected and displayed. Voltage (65 kV) and current (2.5 mA) are fixed with the exposure time varying based on patient type, detector type, and anatomical feature. Exposures can be completed using the trigger. The device can be used with three detector types: film, digital imaging intraoral sensors, and phosphor plates.

User warnings and markings will be on the upper portion of the device near the user interface. Technical and regulatory markings will be on the underside of the device, top of the handset (not visible when attached to device), and bottom of charging cradle.

Principles of Operation: The NOMAD Pro 3 Handheld X-ray System is used like any other extraoral dental X-ray source for intraoral application. An image receptor, such as film, is placed in the patient's oral cavity behind the teeth. The device is powered on, and the appropriate exposure time is set by the operator. The operator should follow appropriate instructions to ensure proper alignment of the X-ray beam to the receptor, and proper positioning of the receptor in the patient's mouth. To prevent inadvertent exposure to X-rays, the operator must first press and release the trigger to enable and then ready the device. A flashing green ENABLED indicator light and an audible signal confirm that the NOMAD Pro 3 Handheld X-ray System is enabled. X-rays are initiated by pulling and holding the trigger on the handle for the duration of the exposure. The system has numerous alarms and alerts to communicate with the operator.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The NOMAD Pro 3 Handheld X-ray System is indicated for use only by a trained and qualified dentist or dental technician for both adult and pediatric subjects as an extraoral diagnostic dental X-ray source to produce X-ray images using intraoral image receptors.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Indications for Use is identical to the Indications for Use of the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

Details of the similarities between subject and predicate devices:

The similarities between Subject Device and the Predicate Device are the Indications for Use as well as the Subject's Device most of the technological characteristics, such as : the energy source which is provided by the same Rechargeable 21.6 C DC Li-Ion battery core pack, or the user interface which allows the selection of several user-selectable preset time, the same as the predicate's device. The hard-shell case and the exposure switch, which has the trigger located on the handset, are as well the same as the predicate. The Battery specifications, starting with the capacity of 1.7 A-Hr. Enabling a recharge capability of 70% remaining capacity after 300 cycles to the duty cycle of 1:60 to the waveform which is constant potential (DC) and the device mA of 2.5 fixed are exactly the same as the predicate device.

Details of the differences between subject and predicate devices:

There are no major differences, however, there are some minor differences between Subject Device and Predicate Device. The differences originate from the device weight and dimensions which are adapted to 6.4 lbs. a very light increase of 0.4 lbs. from the 6.0 lbs. of the predicate device for the weight and as well the device dimensions which are being adjusted to 10.7"L x 11.6"H x 6.25"W from the predicate's device 11"L x 10.5"H x 5.5"W. The Backscatter radiation protection of 6.25" remains the same for the subject device as well as the source to skin distance, remaining at 21cm. The backscatter shield will be comprised of either bismuth-acrylic or lead-acrylic; the predicate device used only lead-acrylic. The exposure time adjusts to 0.04 – 1.0 seconds in 0.01 increments from the predicate's 0.02 – 1.0 seconds in 0.01 increments due to the removal of the timer settings of 0.02 and 0.03, and the subject device kVp value passing as well to 65kVp from the predicate's 60kVp. As a final adjustment for the subject device, the control mechanism tube lists as an Analog control system for the kV & mA values which is a rephrasing from the predicate's programmable logic device for the same values.

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

ISO 14971 Third Edition 2019-12; Medical devices - Application of risk management to medical devices
IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION; Medical devices - Part 1: Application of usability engineering to medical devices
IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION; Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ISO 10993-5 Third edition 2009-06-01; Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-1 Fifth edition 2018-08; Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-12 Fifth edition 2021-01; Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
ISO 10993-23 First edition 2021-01; Biological evaluation of medical devices - Part 23: Tests for irritation
ISO 10993-10 Fourth edition 2021-11; Biological evaluation of medical devices - Part 10: Tests for skin sensitization
ISO 10993-2 Third edition 2022-11; Biological Evaluation of medical devices - Part 2: Animal welfare requirements
IEC 60601-1-3 Edition 2.2 2021-01 CONSOLIDATED VERSION; Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-2-65 Edition 1.2 2021-05 CONSOLIDATED VERSION; Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral-X-ray equipment
IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION; Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Note: This standard is recognized with relevant US national differences applied see references #1 and #2 in the Relevant FDA Guidance and/or Supportive Publication section below.
IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION; Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION; Medical device software - Software life cycle processes
ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]; Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 MOD) [Including Amendment 2 (2021)]

Bench comparison testing demonstrated that NOMAD Pro 3 produced diagnostic-quality intraoral images on both adult and pediatric phantoms equivalent to or better than the predicate device at matched exposures, and all evaluation cases passed. Compliance testing verified the NOMAD Pro 3 met all applicable essential performance and safety requirements, with all standards clauses evaluated passing. Compliance testing confirmed that NOMAD Pro 3 satisfied radiation protection, filtration, leakage radiation, HVL, and beam limitation requirements, with all measured conditions meeting acceptance criteria.

Filtration, kV, and preset characterization testing demonstrated that increased filtration and 65 kV operation maintained or improved image quality without adverse effects, and no test elements failed. Scatter radiation characterization at 65 kV with lead and bismuth shields showed that operator exposure remained below regulatory dose thresholds under worst case conditions, and no measurements exceeded applicable limits. Design verification testing of the backscatter shield confirmed that drop performance, dimensional inspection met acceptance criteria, and backscatter radiation measurements met all established criteria as below dose limits.

Testing of the high voltage power supply confirmed acceptable electrical performance before and after mechanical shock events, and all required output stability evaluations passed. Environmental, mechanical, ingress protection, lifetime cycling, and attachment strength evaluations of the new housing design all passed, confirming suitability of the updated housing. Impedance testing of the new housings demonstrated uniformly low impedance values supporting improved electromagnetic interference mitigation, with all readings within acceptable ranges. Evaluation confirmed correct short shot event detection, linearity of X ray output, and proper operation of new keypad/trigger hold diagnostic indicators, with all functional checks passing.

Clinical data is not needed to characterize performance and establish substantial equivalence. The non-clinical test data characterize all performance aspects of the device based on well-established scientific and engineering principles. Clinical testing has not been conducted on this product. In lieu of clinical studies, the device was evaluated using adult and pediatric phantoms incorporating real teeth and bone to simulate clinically relevant anatomical conditions. In addition, step wedge testing was performed to further characterize device performance across a range of tissue equivalent densities. The step wedges represent varying anatomical features, from thin soft tissue equivalent sections through the thickest steps corresponding to teeth and bone. These evaluations collectively provide a robust assessment of the device's performance under expected conditions of use.

As a result of the non-clinical tests performed in the summary above, all acceptance criteria are fulfilled and tests passed in accordance with product's functional requirement specifications and applicable standards. The verification and validation testing performed was considered adequate in supporting a substantial equivalence determination. Based on the tests performed, it can be determined that the proposed device is substantially equivalent in performance aspects to the predicate device.

Conclusion:
Based on a comparison of intended use, indications for use, technological characteristics, principle of operation, features, and

performance data, the device NOMAD Pro 3 is deemed to be substantially equivalent to the predicate device KaVo NOMAD Pro 2 as it satisfies all criteria of substantial equivalence and does not raise new concerns regarding substantial equivalence: (1) Indications for Use, (2) Technological Characteristics, and (3) Performance Data. NOMAD Pro 3 does not introduce fundamentally new scientific technology, and the nonclinical tests demonstrate that the device is substantially equivalent.