September 24, 2025

Dentimax, Inc
% David Arnett
4115 E. Valley Auto Drive
Suite 101
MESA, AZ 85206

Re: K251206
Trade/Device Name: Digital X-Ray DentiMax Pro Imaging System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: Class II
Product Code: MUH
Dated: April 10, 2025
Received: August 19, 2025

Dear David Arnett:

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.

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,

FDA Digitally signed by Gabriela M. Rodal -S for

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

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.

510(k) Number *(if known)*
K251206

Device Name
Digital X-Ray DentiMax Pro Imaging System

Indications for Use *(Describe)*

The Digital X-Ray DentiMax Pro Imaging System is intended to be used with standard digital X-ray systems to collect dental x-rays photons and convert them into dental images that may be stored, viewed, and manipulated by dentists for the diagnosis of disease of the teeth, jaw, and oral structures.

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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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K251206

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
K251206

(As Required by 21 CFR 807.92)

1. **Date Prepared [21 CFR 807.92(a)(1)]**

   September 17, 2025

2. **Submitter's Information [21 CFR 807.92(a)(1)]**

Company Name:	DENTIMAX, INC
Company Address:	4115 E. Valley Auto Drive, Suite 101 Mesa, AZ 85206
Contact Person:	David J. Arnett
Phone:	(480) 396-1798
Email:	david@dentimax.com

3. **Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]**

Trade Name:	Digital X-Ray DentiMax Pro Imaging System
Common Name:	Intraoral X-Ray Imaging System
Model Name:	ProSystem2 ProSystem1.5 ProSystem1
Classification Name:	Extraoral Source X-Ray System
Product Code:	MUH
Regulation Number:	21 CFR 872.1800
Device Class:	II

4. **Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]**

   The identification predicates within this submission are as follows:

Manufacturer:	DENTIMAX, INC
Trade Name:	DentiMax Digital X-Ray Imaging System
Model Name:	SENSORH1

	SENSORH2
Product Code:	MUH
Classification Name:	Extraoral Source X-Ray System
FDA 510 (k) #:	K092547
Regulation Number:	21 CFR 872.1800
Device Class:	II

5. Description of the Device [21 CFR 807.92(a)(4)]

The Digital X-Ray DentiMax Pro Imaging System consists of intraoral digital sensors and the optional DentiMax Imaging Software application. This system provides image acquisition, storage, and display functions for dental radiography. The digital intraoral x-ray sensors are based on complementary metal-oxide semiconductor (CMOS) technology. A scintillating material converts the incident x-rays into visible light, the light is coupled optically to a CMOS technology light detection imager and then is converted to digital data. A high-speed direct USB interface enables a simple connection to a computer without need for an additional control box. The design of the sensor assembly supports the automatic detection of incident x-rays to generate digital images for intraoral applications, once armed via a software command. The DentiMax Imaging Software application functions as a viewing software for image acquisition, enhancement, and display; however, it is not required for use of the sensors. The sensors are also compatible with other FDA-cleared dental imaging software commonly available in the marketplace. The optional DentiMax positioner kit helps ensure the system is aligned correctly to capture accurate dental images. The major function of the Digital X-Ray DentiMax Pro Imaging System is to convert X-rays into high-resolution digital images suitable for dental diagnostic use.

6. Indications for Use [21 CFR 807.92(a)(5)]

The Digital X-Ray DentiMax Pro Imaging System is intended to be used with standard digital X-ray systems to collect dental x-rays photons and convert them into dental images that may be stored, viewed, and manipulated by dentists for the diagnosis of

disease of the teeth, jaw, and oral structures.

7. Technological Characteristics [21 CFR 807.92(a)(6)]

Materials, design, energy source, other features.

Item	Predicate Device: DentiMax Digital X-Ray Imaging System	Proposed Device: Digital X-Ray DentiMax Pro Imaging System
510(K) Number:	K092547	To be assigned
Classification Name:	Extraoral Source X-ray System	Same
Product Code:	MUH	Same
Regulation Number:	21 CFR 872.1800	Same
Panel:	Radiology	Same
Classification:	II	Same
X-Ray Absorber (Scintillator):	CsI	Same
Installation Type:	Portable	Same
Detector Structure:	CMOS Photodiode Array	Same
Dimensions:	SENSORH1: 41mm×26.4mm×5.8mm SENSORH2: 42.3mm×30mm×5.8mm	ProSystem1: 36.3mm×24.5mm×7.8mm ProSystem1.5: 38.8mm×29.6mm×8.3mm ProSystem2: 41.8mm×30.4mm×8.3mm
Image Matrix Size:	1500×1000 pixels for SENSORH1; 1700×1200 pixels for SENSORH2	1552×1042 pixels for ProSystem1; 1700×1346 pixels for ProSystem1.5 1850×1346 pixels for ProSystem2

Effective Imaging Area:	30mm×20mm for SENSORH1 34mm×24mm for SENSORH2	30mm×20mm for ProSystem1 33mm×26mm for ProSystem1.5 36mmx26mm for ProSystem2
Spatial Resolution:	10 lp/mm	20 lp/mm
Modulation Transfer Function:	0.1 at 7 lp/mm	0.1 at 17 lp/mm
DQE:	Not available (per predicate)	0.3 at 1 lp/mm 0.2 at 2 lp/mm 0.1 at 3 lp/mm
Power Consumption:	DC +4.5 to 5.5V (480mA Max.)	DC +4.5 to 5.5V (350mA Max.)
Communications:	USB 2.0	Same
Protection against shock:	Type BF applied part	Same
Operation:	Temperature: 0 to 50ºC Humidity: 0 to 70% (Non-Condensing)	Temperature: 5 to 30º Humidity: 30 to 75% (Non-Condensing)
Storage and Transportation:	Temperature: -10 to 70ºC Humidity: 10 to 95% (Non-Condensing)	Temperature: -40 to 70ºC Humidity: 10 to 95% (Non-Condensing)

8. Nonclinical study

1) Electrical Safety and EMC Testing:
   Electrical, mechanical, environmental safety and performance testing according to IEC/ES 60601-1 and IEC 60601-2-65 were performed, and EMC testing was also conducted in accordance with IEC 60601-1-2. All test results meet the standard requirements.
2) Biological Evaluation:

   Although there is a single-use protective sheath prior to each use, the materials of the

intra-oral sensor enclosure which may contact patient's oral mucosa have been evaluated with the ISO10993-1. And the evaluation results and test result assured the safety the same as the predicate device. The sensor position frame is evaluated and assured the safety the same as the predicate device.

3) Nonclinical Considerations:

According to the *Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices,* the non-clinical studies have been performed and the results have shown that the Digital X-Ray DentiMax Pro Imaging System is substantially equivalent to the predicate device on the market (K092547).

Bench testing was performed on the Digital X-Ray DentiMax Pro Imaging System to evaluate image quality parameters such as resolution, signal response, efficiency, and noise. The results demonstrated consistent performance across production units, meeting expectations for diagnostic dental radiography.

According to the FDA guidance document *Content of Premarket Submissions for Device Software Functions*, the DentiMax Imaging Software classifies the hazards, defines requirements specification and design specification, and all the specifications pass all the test cases and complies with the intended design requirements.

In addition, cybersecurity testing of the subject device was performed in accordance with the FDA guidance document *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*. The evaluation included threat modeling, secure software design controls, and verification of safeguards to ensure protection against cybersecurity risks.

4) Clinical Consideration:

A clinical image evaluation study was performed to confirm performance under routine dental use. A representative sample of adult and pediatric patients were imaged using the Digital X-Ray DentiMax Pro Imaging System. Independent board-certified dentists reviewed the images and confirmed diagnostic quality consistent with clinical expectations.

9. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, DentiMax, Inc.

concludes that the Digital X-Ray DentiMax Pro Imaging System is substantially equivalent to predicate device in intended use, safety and effectiveness, and technical characteristics.