October 6, 2023

Denti.AI Technology, Inc.
℅ Donna-Bea Tillman
Senior Consultant
Biologics Consulting
100 Daingerfield Road, Suite 400
ALEXANDRIA, VA 22314

Re: K230144
Trade/Device Name: Denti.AI Detect
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical Image Analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: September 6, 2023
Received: September 6, 2023

Dear Donna-Bea Tillman:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
DHT8B: Division of Radiologic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230144

Device Name
Denti.AI Detect

Indications for Use *(Describe)*
Denti.AI Detect is a Computer-Assisted Detection (CADe) software device intended to be used by dental professionals, comprising dentists and dental specialists, while reading extraoral and intraoral 2D dental radiographs.
The device aims to assist in detecting and highlighting uncategorized regions of interest (ROIs) within the teeth area, which include caries and periapical radiolucency, as a second reader. The device is also intended to aid in the measurements of mesial and distal bone levels associated with each tooth.
The device is aimed to be used with images from the patients of 22 years age and older without remaining primary dentition. The device is not intended to replace a complete clinician's review or clinical judgment that considers other relevant information from the image or patient history.

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.

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92 the 510(k) Summary for the Denti.AI Detect is provided below.

1. SUBMITTER

Applicant:	Denti.AI Technology Inc. 99 Yorkville Ave, Suite 214 Toronto, Ontario, Canada M5R3K5
Contact/Submission Correspondent:	Donna-Bea Tillman, Ph.D. Biologics Consulting Group 100 Daingerfield Road, Suite 400 Alexandria, VA 22314 (410) 531-6542 dtillman@biologicsconsulting.com
Date Prepared:	October 5, 2023

2. DEVICE

Device Trade Name:	Denti.AI Detect
Device Common Name:	Medical Image Analyzer
<u>Primary Classification</u>	
Classification Name	892.2070 Medical Image Analyzer
Regulatory Class:	II
Product Code:	MYN
<u>Secondary Classification</u>	
Classification Name	892.2050 Picture Archive and Communication System
Regulatory Class:	II
Product Code:	LLZ

3. PREDICATE DEVICE

Primary Predicate:	Pearl Second Opinion (K210365)
Secondary Predicate:	Overjet Dental Assist (K210187)

4. DEVICE DESCRIPTION

Denti.AI Detect is a prescription use Computer-Assisted Detection (CADe) device aimed to assist dentists and dental specialists in detecting and highlighting regions of interest (ROIs) within the teeth area, which include caries and periapical radiolucency. The device is also intended to aid in the measurements of medial and distal bone levels associated with each tooth.

5. INTENDED USE/INDICATIONS FOR USE

Denti.AI Detect is a Computer-Assisted Detection (CADe) software device intended to be used by dental professionals, comprising dentists and dental specialists, while reading extraoral and intraoral 2D dental radiographs.

The device aims to assist in detecting and highlighting uncategorized regions of interest (ROIs) within the teeth area, which include caries and periapical radiolucency, as a second reader. The device is also intended to aid in the measurements of mesial and distal bone levels associated with each tooth.

The device is aimed to be used with images from the patients of 22 years age and older without remaining primary dentition. The device is not intended to replace a complete clinician's review or clinical judgment that considers other relevant information from the image or patient history.

6. SUBSTANTIAL EQUIVALENCE

Comparison of Intended Use/Indications for Use

Both the subject device and the primary predicate device are Computer-Assisted Detection software devices intended to be used by dental professional as a second reader to identify and mark dental findings in 2D dental radiograph. While the supported age range for the subject Denti.AI device is more limited than that of the Pearl predicate (22 years and older versus 12 years and older), both devices are only intended to be used on permanent teeth. The types of findings detected by the subject device are slightly different from those detected by the predicate device, but the intended use of both is the same, namely to detect findings of interest.

The intended use of the subject device for measuring mesial and distal bone level is the same as that of the Overjet secondary predicate device. Both devices are intended to be used to support dental professionals in conjunction with a full patient evaluation. The slight differences in features do not change the intended use of the device which is to provide measurements to trained dental professionals.

Technological Comparisons

Table 1 compares the key technological feature of the subject devices to the predicate devices: Pearl Second Opinion (K210365) and Overjet Dental Assist (K210187).

Table 1: Technological Comparison

	Subject Device	Primary Predicate Device	Secondary Predicate Device
510(k) Number	K230144	K210365	K210187
Applicant	Denti.AI	Pearl	Overjet
Device Name	Detect	Second Opinion	Dental Assist
Classification Regulation	892.2070 Medical Image Analyzer 892.2050 Picture Archive and Communication System	892.2070 Medical Image Analyzer	892.2050 Picture Archive and Communication System
Product Code	MYN LLZ	MYN	LLZ
Prescription Use	Yes	Yes	Yes
Intended Users	Dentists and Dental Specialists	Dental health professionals	Trained professionals including, but not limited to, dentists and dental hygienists
Patient Population	Adults 22 years of age and older with permanent dentition	Patients 12 years and older with permanent teeth	Adults 22 years of age and older
Platform	Cloud-based	Windows 7	Cloud-based
Imaging Modality	Intraoral (bitewing, periapical) Extraoral (panoramic)	Intraoral (bitewing, periapical)	Intraoral (bitewing, periapical)
Supported File formats	jpeg, jpg, tiff, tif, png, bmp, DICOM	RVG, DICOM, JPEG, TIFF, and PNG and converts to JPEG	jpg, png, jfif, eop, etp, jif
Detection Findings	Caries and Periapical radiolucency	Caries, Discrepancy at the margin of an existing restoration, Calculus, Periapical radiolucency, Crown (metal, including zirconia & non-metal), Filling (metal & non-metal), Root canal, Bridge and Implants.	N/A
Reader Workflow for Detection	Second Reader	Second Reader	N/A

	Subject Device	Primary Predicate Device	Secondary Predicate Device
Measurements	Mesial and distal bone levels associated with each tooth	N/A	Mesial and distal bone levels associated with each tooth

7. PERFORMANCE DATA

Biocompatibility Testing

There are no direct or indirect patient-contacting components of the subject device. Therefore, patient contact information is not needed for this device.

Electrical safety and electromagnetic compatibility (EMC)

Not applicable. The subject device is a software-only device. It contains no electric components, generates no electrical emissions, and uses no electrical energy of any type.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a Moderate Level of Concern as a malfunction of, or a latent design flaw in, the Software Device could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that could lead to Minor Injury. Verification of the software was conducted to ensure that the product works as designed. Validation was conducted to validate the design and performance of the product.

Bench Testing

Stand-alone studies were conducted to assess the performance of the Denti.AI Detect system for 1) detecting suspicious ROIs (caries and periapical radiolucencies); and 2) making measurements of distal and mesial bone levels associated with each tooth on a range of intraoral and extraoral radiographs.

The caries and periapical radiolucency study included 709 images obtained from 6 sites in the US. Study subjects aged in range from 22 to 92 and were roughly split between males and females. Ground truthing was performed by three independent dentists with the consensus rule applied to establish final reference standard. The primary endpoint for the study was to show that the lower bound of the 95% CI of the across-category wAFROC AUC exceeds the predefined threshold of 0.6. The study met its primary endpoint with an across-category wAFRPOC AUC of 0.737 and a 95% CI of (0.713, 0.761).

The bone measurement study included 193 images obtained from 9 sites in the US. Study subjects aged in range from 22 to 88 and were roughly split between males and females. Ground

truthing was performed by three independent dentists with majority rule applied to establish final reference standard. The primary study endpoints and results are shown in Table 2.

Table 2: Primary Study Endpoints and Results

Endpoint	Results (95% CI)
Bitewing: CEJ-Bone: Sensitivity	98.1% (96%, 99.5%)
Bitewing: CEJ-Bone: Specificity	93% (88.7%, 96.7%)
Bitewing: CEJ-Bone: MAE	0.513 mm (0.444 mm, 0.593 mm)
Bitewing: CEJ-Bone/CEJ-Root Ratio: MAE	3.8% (3.3%, 4.4%)
Periapical: CEJ-Bone: Sensitivity	98.2% (96.2%, 99.7%)
Periapical: CEJ-Bone: Specificity	88.5% (82.8%, 93.4%)
Periapical: CEJ-Bone: MAE	0.572 mm (0.497 mm, 0.653 mm)
Periapical: CEJ-Root: Sensitivity	96.9% (94.2%, 99%)
Periapical: CEJ-Root: Specificity	92.2% (87.9%, 96%)
Periapical: CEJ-Root: MAE	0.735 mm (0.612 mm, 0.868 mm)
Periapical: CEJ-Bone/CEJ-Root Ratio: MAE	4.3% (3.7%, 4.9%)
Extraoral: CEJ-Bone-Root: Sensitivity	91.6% (89.6%, 93.6%)
Extraoral: CEJ-Bone-Root: Specificity	84.3% (70.8%, 95.8%)
Extraoral: CEJ-Bone/CEJ-Root Ratio: MAE	4.7% (4%, 5.5%)

All of the Acceptance Criteria were met with the exception of the CEJ-Bone Specificity on Periapical images, where the lower CI bound was slightly less than the Acceptance Criterion.

Animal Testing

Not applicable. Animal studies are not necessary to establish the substantial equivalence of this device.

Clinical Data

A fully crossed Multi-Reader Multi-Case (MRMC) study was conducted to evaluate the Denti.AI Detect device's effect on dental professionals' performance in detecting periapical radiolucencies and caries on a range of intraoral and extraoral radiographs. A total of 154 images taken from 5 sites located across the US were included in the study. The study enrolled 24 dental professionals who were asked to evaluate each of the images under two conditions: an unaided read followed by a computer-aided read. The results demonstrated a statistically significant improvement in across-category reader performance when assisted by Denti.AI Detect as compared to when unassisted (aided wAFROC 0.809, unaided wAFROC 0.784, difference 0.025, p-value 0.029).

8. CONCLUSION

Denti.AI Detect has the same intended use as the predicate devices: to detect findings of interest and provide measurements on dental X-rays for use by trained dental professionals. While there are some small differences in technological characteristics between the subject device and the predicate devices, these differences do not raise different questions of safety and effectiveness. The results of the stand-alone and reader studies demonstrate that the performance of Denti.AI

Detect is equivalent to that of the predicate devices, and Denti.AI has demonstrated that the device complies with applicable Special Controls for Medical Image Analyzers. Therefore, Denti.AI Detect can be found substantially equivalent to the predicate devices.