November 22, 2022

Denti.AI Technology Inc.
% Donna-Bea Tillman
Senior Consultant
Biologics Consulting
1555 King Street
ALEXANDRIA, VA 22314

Re: K222054
Trade/Device Name: Denti.AI Auto-Chart
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: October 25, 2022
Received: October 25, 2022

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 2022.11.22 18:06:58 -05'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222054

Device Name
Denti.AI Auto-Chart

Indications for Use *(Describe)*
Denti.AI Auto-Chart is a Medical Image Management and Processing System (MIMPS) device aimed to assist dental professionals (Users), comprising general dentists, dental specialists, and dental hygienists, in detecting dental structures and producing dental charting data based on the interpretation of intraoral and extraoral 2D X-Ray images.

Denti.AI Auto-Chart is intended to assist in:
• Detecting natural dental structures: teeth and missing teeth
• Detecting dental structures added through past restorative treatment: implants, crowns, pontics, endodontic treatment, fillings
• Choosing treatment options
• Producing dental charts based on image analysis results as well as conditions added manually or produced by integrated CAD devices

The device is aimed to be used with images from the adult population only (≥22 years old and do not have remaining primary teeth). The device is not intended as a replacement for 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 Auto-Chart 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 1555 King Street, Suite 300 Alexandria, VA 22314 (410) 531-6542 dtillman@biologicsconsulting.com
Date Prepared:	October 24, 2022

2. DEVICE

Device Trade Name:	Dent.AI Auto-Chart
Device Common Name:	Image Processing System
Classification Name	21 CFR 892.2050 Medical Image Management and Processing System
Regulatory Class:	II
Product Code:	LLZ

3. PREDICATE DEVICE

Predicate Device: Ewoosoft EzOrtho V1.3 (K220003)

4. DEVICE DESCRIPTION

Denti.AI Auto-Chart is a Medical Image Management and Processing System (MIMPS) device aimed to assist dental professionals in detecting dental structures and producing dental charting data based on the interpretation of 2D X-Ray images. The device is intended to assist dental professionals in detecting teeth and missing teeth, numbering teeth, and detecting dental structures added through past restorative treatment, including implants, crowns, pontics, endodontic treatment, and fillings.

5. INTENDED USE/INDICATIONS FOR USE

Denti.AI Auto-Chart is a Medical Image Management and Processing System (MIMPS) device aimed to assist dental professionals (Users), comprising general dentists, dental specialists, and dental hygienists, in detecting dental structures and producing dental charting data based on the interpretation of intraoral and extraoral 2D X-Ray images.

Denti.AI Auto-Chart is intended to assist in:

- Detecting natural dental structures: teeth and missing teeth
- Detecting dental structures added through past restorative treatment: implants, crowns, pontics, endodontic treatment, fillings
- Choosing treatment options
- Producing dental charts based on image analysis results as well as conditions added manually or produced by integrated CAD devices

The device is aimed to be used with images from the adult population only (≥22 years old and do not have remaining primary teeth). The device is not intended as a replacement for a complete clinician's review or clinical judgment that considers other relevant information from the image or patient history.

6. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

Both the subject Denti.AI Auto-Chart and the predicate Ewoosoft EzOrtho are intended for use to create dental charts to track patient information and treatments. Both devices are intended for use by trained dental practitioners who are responsible for making the final clinical decisions. The devices differ in the type of dental treatment (general dentistry for Auto-Chart and orthodontics for EzOrtho), but this does not change the fundamental purpose of the devices which is to create patient records.

Technological Comparisons

Table 1 compares the key technological feature of the subject devices to the predicate device Ewoosoft EzOrtho V1.3 (K220003).

Table 1: Technological Comparison

	Denti-AI Auto-Chart (Proposed Device)	**Ewoosoft EzOrtho V1.3 (K220003) (Predicate Device)**
510(k) Number	TBD	K220003
Applicant	Denti.AI Technology Inc.	Ewoosoft Co., Ltd.
Classification Regulation	CFR 892.2050 Medical Image Management and Processing System	CFR 892.2050 Medical Image Management and Processing System

	Denti-AI Auto-Chart (Proposed Device)	Ewoosoft EzOrtho V1.3 (K220003) (Predicate Device)
Product Code	LLZ	LLZ
Prescription Use	Yes	Yes
Intended Users	Dental professionals	Licensed practitioners or dentists
Patient Population	Adult patients receiving general dental care	Patients receiving orthodontic care
Platform	Cloud-based	IBM-compatible PC or PC network
Imaging Modality	2-D intraoral or extraoral X-rays	Digital camera or radiological imaging device
Supported File formats	jpeg, jpg, tiff, tif, png, bmp, DICOM	bmp, jpg, png, tif, DICOM
Detection Features	Detecting and numbering teeth Detecting and identifying past restorative treatments	Detecting anatomical landmarks
Image manipulation features	Invert, brightness, contrast, sharpen, rotate, flip, annotations, zoom in/out, magnifier	Grayscale, invert, emboss, brightness, contrast, gamma, sharpen, median, despeckle, hue, saturation, equalize flip, mirror, masking, rotate, annotation, cephalometric tracing, implant simulations
Technology	AI-based algorithms for the detection of natural dental structures and structures added through past restorative treatment	AI-based algorithms for detection of various anatomical landmarks

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

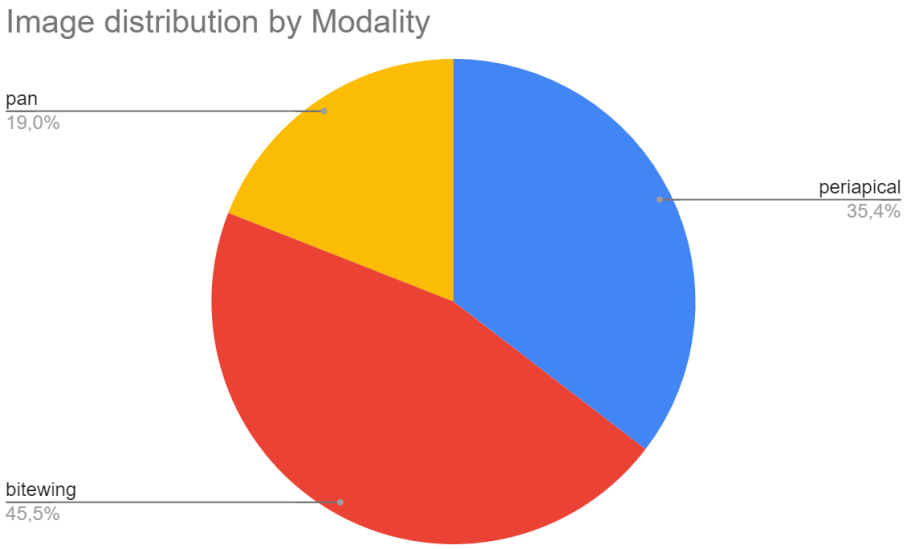
Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a Moderate Level of Concern a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury. Verification of the software was conducted to ensure that the product works as designed. Validation was conducted to check the design and performance of the product.

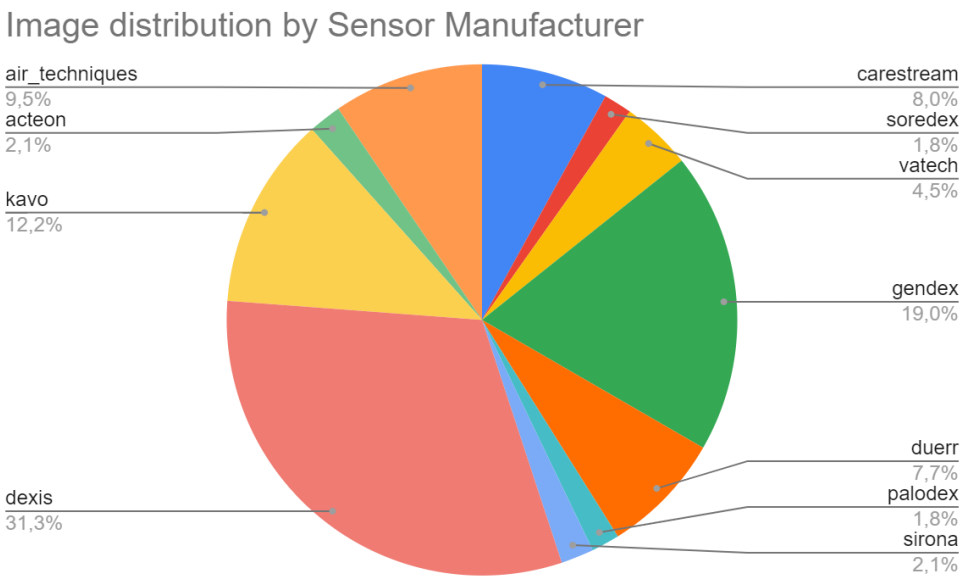
Bench Testing

Denti.AI completed the standalone study according to the predefined protocol to demonstrate the safety and effectiveness of the Denti.AI Auto-Chart device for its indications for use.

Dataset

The testing dataset used in the study consisted of the 336 images (1 image per patient) taken from the multiple dental clinics across the US. The patient population was roughly uniformly distributed by age and gender. The following distribution of imaging modalities and sensor manufacturers were present in the testing dataset:





Reference Standard

The ground truth annotations (GT) were used as the reference standard when measuring the device performance. The GT was established with the help of two experienced dental hygienists with an experienced dentist reviewing cases of disagreement.

Study Results

The primary tests and the metrics are listed in the table below:

- **"Sensitivity (teeth in the field of view)"** of **Teeth Detection** shows the percentage of **actual positive teeth** (teeth annotated in the GT) in the image field of view that are successfully found by the device
- **"PPV"** of **Teeth Detection** shows the percentage of teeth found by the device that are **actual positive teeth**
- **"Overall classification accuracy"** of **Teeth Numbering** shows the percentage of detected teeth that are correctly numbered by the device according to the standard dental notation
- **"Sensitivity averaged across all restoration types"** of **Restorative Findings Identification** shows the percentage of **actual positive teeth** (teeth showing the restorative finding in the GT with the matching restoration type) that are successfully classified by the device as **positive**
- **"Specificity averaged across all restoration types"** of **Restorative Findings Identification** shows the percentage of **actual negative teeth** (teeth that do NOT show the restorative finding in the GT with the matching restoration type) that are successfully classified by the device as **negative**
- **"Classification accuracy averaged across all findings"** of **Binding Dental Findings to Teeth** shows the percentage of findings that are associated with the correct tooth

- **"Classification accuracy averaged across all types"** of **Classifying Filling By Type** shows the percentage of teeth with detected fillings that are correctly classified by the filling type
- **"Classification accuracy averaged across all surfaces"** of **Classifying Filling By Surface** shows the percentage of teeth with detected fillings that are correctly classified by affected surfaces
- **"Classification accuracy"** of **Classifying Crowns by Type** shows the percentage of teeth with detected crowns that are correctly classified by the crown type
- **"Manual charting reduction rate"** of the **Summary Performance** shows the percentage of **reduction in the number of manual operations** when pre-filling the charting data with **Denti.AI Auto-Chart** compared to entering all the charting records manually

Test ID	Test Name	Metric	Value	95% Confidence Interval
1	Teeth Detection	Sensitivity (teeth in the field of view)	97.4%	(96.6%, 98.2%)
		PPV	99.6%	(99.3%, 99.9%)
2	Teeth Numbering	Overall classification accuracy	85.9%	(82.6%, 88.9%)
3	Restorative Findings Identification	Sensitivity averaged across all restoration types	88.5%	(86.1%, 90.6%)
		Specificity averaged across all restoration types	98.3%	(97.8%, 98.7%)
4	Binding Dental Findings to Teeth	Classification accuracy averaged across all findings	98.3%	(97.5%, 99.0%)
5	Classifying Filling By Type	Classification accuracy averaged across all types	98.0%	(96.9%, 98.9%)
6	Classifying Filling By Surface	Classification accuracy averaged across all surfaces	88.9%	(87.0%, 90.7%)
7	Classifying Crowns by Type	Classification accuracy	94.8%	(92.2%, 97.1%)
8	Summary Performance	Manual charting reduction rate	71.2%	(68.2%, 74.1%)

Conclusions

All conducted tests produced results that exceeded predefined acceptance criteria. The **Summary Performance "Manual charting reduction rate"** metric shows that the number of manual operations **is reduced by over 70%** when using **Denti.AI Auto-Chart** for initial dental chart pre-filling compared to the fully manual entry of the same dental charting information.

Stratified analysis **by patient gender and age** demonstrated that there is no significant difference in any of the reported endpoints. Stratified analysis **by sensors** demonstrated the overall high level of generalizability: no sensor is a clear outlier. Stratified analysis **by modality** demonstrated differences in two main endpoints:

- **Classification accuracy of teeth numbering** is higher on extraoral images. This difference can be explained by the fact that extraoral images show a full mouth picture, whereas intraoral images show only a segment of the jaw, sometimes as few as 3-4 teeth. Numbering teeth on intraoral images is naturally more challenging than on panoramic images

- **Restorative Findings Identification sensitivity metric** is higher on intraoral images. The main difference is in detecting crowns and fillings, whereas the performance in detecting implants and endodontic treatments is close for each modality. The difference can be explained by the fact that intraoral images have a much higher spatial resolution compared to panoramic images

While having some natural tradeoffs in terms of producing charting data, both modalities demonstrated close estimates of Summary Performance metrics ("Manual charting reduction rate")

Animal Testing

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

Clinical Data

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

8. CONCLUSION

The predicate device and subject device have the same intended use, as they are both intended for use to create dental charts to track patient information and treatments. Both devices are intended for use by trained dental practitioners who are responsible for making the final clinical decisions. Although there are technical differences, as discussed above, these differences in technological characteristics do not raise different questions of safety and effectiveness. The predefined Acceptance Criteria established for the stand-alone study are based on the current state of dental practice and are appropriate to demonstrate that Auto-Chart performs in accordance with specifications and will meet user needs and intended uses.

Based on the detailed comparison between the predicate devices and the subject devices, the software verification testing and performance testing, the Denti.AI Auto-Chart can be found substantially equivalent to the predicate device.