Overjet, Inc.
% Mr. Adam Heroux
Head of Regulatory Affairs
560 Harrison Ave, Unit 403
BOSTON MA 02118

May 19, 2021

Re: K210187
Trade/Device Name: Overjet Dental Assist
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: April 12, 2021
Received: April 21, 2021

Dear Mr. Heroux:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210187

Device Name

Overjet Dental Assist

Indications for Use *(Describe)*

Overjet Dental Assist is a radiological semi-automated image processing software device intended to aid dental professionals in the measurements of mesial and distal bone levels associated with each tooth from bitewing and periapical radiographs.

It should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis. The system is to be used by trained professionals including, but not limited to, dentists and dental hygienists.

Intended Patient Population:

The intended patient population of the device is patients living in the United States, who are 22 years old or older, and that do not have any remaining primary teeth. Overjet has not evaluated the performance of the device on primary dentition.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

(K210187)

This summary of 510(k) information is being submitted in accordance with the requirements of 21CFR Part 807.92

1. Date
   4/12//2021

2. Applicant

   Overjet, Inc.
   560 Harrison Ave
   Unit 403
   Boston, MA 02118
   Contact Person: Adam Heroux
   Email: adam@overjet.ai

3. Trade Name
   Overjet Dental Assist

4. Common Name
   Dental Imaging Software

5. Classification
   System, Imaging processing, radiological (21CFR 892.2050, Product code LLZ, Class 2, Radiology)

6. Device Description

   Overjet Dental Assist developed by Overjet Inc, is a radiological semi automated image processing software device intended to aid dental professionals in the measurements of mesial and distal bone levels associated with each tooth from bitewing and periapical radiographs.

   Overjet Dental Assist is a cloud native Software as a Medical Device that allows users to automate the measurement of interproximal bone levels for bitewing and periapical radiographs, review associated radiographs, view annotations, modify annotations.

7. Indications for Use

   Overjet Dental Assist is a radiological semi-automated image processing software device intended to aid dental professionals in the measurements of mesial and distal bone levels associated with each tooth from bitewing and periapical radiographs.

It should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis. The system is to be used by trained professionals including, but not limited to, dentists and dental hygienists.

Intended Patient Population:

The intended patient population of the device is patients living in the United States, who are 22 years old or older, and that do not have any remaining primary teeth. Overjet has not evaluated the performance of the device on primary dentition.

8. Predicate Device

Device - EZOrtho
Manufacturer - Ewoosoft Co., Ltd.
510k - K192888

9. Substantial Equivalence

Device	Ewoosoft EZOrtho v1.0 (predicate)	Overjet Dental Assist (proposed)
510k	K192888	K210187
Indications	EzOrtho is a software indicated for use by dentists who provide orthodontic treatment for image analysis, simulation, profilogram, VTO/STO and patient consultation. Results produced by the software's diagnostic, treatment planning and simulation tools are dependent on the interpretation of trained and licensed practitioners or dentists	Overjet Dental Assist is a radiological semi-automated image processing software device intended to aid dental professionals in the measurements of mesial and distal bone levels associated with each tooth. It should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis. The system is to be used by trained professionals including, but not limited to, dentists and dental hygienists
Patient Population	Patients receiving dental care	Patients receiving dental care
Platform	IBM-compatible PC or PC network	Web - Edge, Chrome, Firefox
OS	Microsoft Window 7, 8, 10	any

User Interface	Mouse, Keyboard	Mouse, Keyboard, Trackpad
Image Input Sources	Images can be scanned, loaded from digital cameras or card readers, or imported from a radiographic imaging device	Images imported from the radiographic device, or from the practice management system
Image format	DICOM, BMP, JPG, PNG, TIF	jpg, png, jfif, eop, etp, jif
Patient Database Compatibility	SQL	SQL
Includes Image Measurement tools	Linear distance, angle	Linear distance
Image viewing	Full, side by side, thumbnail	Full, Thumbnail
Image manipulation	Grayscale, invert, emboss, brightness, contrast, gamma, sharpen, median, despeckle, hue, saturation, equalize flip, mirror, masking, rotate, annotation, cephalometric tracing, implant simulations	annotation
Cephalometric tracing	In addition to the user-configured analysis, standard orthodontic tracing analysis include: Downs Jarabek McNamara Ricketts Jefferson	n/a
Implant module	Generic	n/a
3D imaging capability	None	none
Image annotation	Text, paint, ellipse, pointer, select, draw, magnify, line, rectangle, ruler, protractor, brush, select region, copy / paste	Line

Overjet Dental Assist is determined to be substantially equivalent to the Ewoosoft EZ Ortho cleared as K192888. Both systems are software intended to support dental professionals in their diagnosis and treatment planning for their dental patients.

Both software systems automatically annotate dental radiographs for the dentist. EZ Ortho places calibration points within a radiograph for orthodontic planning, while the Overjet Dental Assist utilizes key points to measure interproximal bone levels. Both systems allow users to visualize the radiograph with the annotations, add their own annotations, and use the information as part of their diagnostic process.

Other similarities include both systems have no direct contact with the patient, both systems evaluate oral cavity radiographs, both systems utilize standard image types, and both systems connect to practice management systems.

Some differences between the systems include the location of the software, the user interface, and the availability of additional features. A primary difference is the EZ Otho is a local software while Overjet Dental Assist is a cloud native application. While EZ Ortho and Overjet Dental Assist have different user interfaces, both are accessed by computer and are intended for dental professionals to review annotations on dental radiographs. The EZ Ortho software contains additional annotation features that are not required for the Overjet Dental Assist use case. Overjet does not feel that the differences raise a concern of substantial equivalence and these differences do not interfere with the ability of the Overjet software to achieve its intended use.

10. Performance Testing

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, since a failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

Bench Testing

Bench testing included evaluation of performance based upon a ground truth data set utilizing Object Keypoint Similarity assessment. Overjet Dental Assist was evaluated with two datasets of 2234 bitewing radiographs, and 6543 periapical radiographs and evaluated the precision and recall against the labeled keypoints within those radiographs. The Overjet met acceptable performance criteria with the following results:

Metric	Bitewing	Periapical
Average Precision	82.3%	83.0%
Average Recall	89.5%	90.0%

Clinical Testing

Clinical testing of the Overjet Dental Assist software was performed utilizing retrospective clinical subject data from 65 bitewing and 96 periapical radiographs from 63 subjects. The demographics of the data set was as follows:

Subject Age	Count (%)
under 30	15 (24%)
30-40	9 (14%)
40-50	8 (13%)
50-60	12 (19%)
60-70	6 (10%)
70 +	12(19%)
no information provided	1 (1%)

Subject Gender	Count (%)
F	46 (73%)
M	17 (27%)

No information about ethnicity was available from the dental radiographs.

Overjet utilized three US licensed dentists to label interproximal bone levels using the measurement tool in Dexis Webview software for all of the radiographs. These measurements were then adjudicated by two US Dental Radiologists. The final adjudicated measurements were compared against the Overjet Dental Assist predicted measurements.

The Overjet Dental Assist software met the prespecified acceptance criteria of >85% sensitivity and specificity when compared to the ground truth, and accuracy of <1.5mm mean absolute difference versus ground truth.

The Overjet Dental Assist software demonstrated a modeled 98.7% sensitivity value and 95.0% specificity value, and a mean absolute difference from the ground truth of 0.307mm for measurement of interproximal bone levels in bitewing radiographs. In interproximal bone levels in periapical radiographs, Overjet Dental Assist scored 88.94% sensitivity, 95.96% specificity, and 0.353mm mean absolute difference. Performance of measurement of Periapical Root Length was measured at 90.9% sensitivity, 97.47% specificity, and 0.567mm mean absolute difference.

The interproximal bone level value in periapical images while meeting the performance acceptance criteria, did not meet the alpha value of <0.05. The alpha for the hypothesis test was 0.083. Analysis of this data indicated that 33% of the false negatives were

related to anatomical overlap that obstructed the CEJ point. In this case human readers were more prone to estimate a bone level point that was obscured. The overall sensitivity of 88% was consistent with the performance of the three ground truth dentists.

No adverse effects or complications were recorded associated with this study as all radiographs were retrospective and no treatment decisions were made.

All testing demonstrated that the Overjet Dental Assist software met prespecified performance requirements when evaluated against human labeling.

11. Conclusion

Overjet Dental Assist is substantially equivalent to the predicate device, EZ Ortho. Differences do not raise any concerns about the safety or efficacy of the device.