September 21, 2023

Overjet, Inc.
% Deepthi Paknikar
Regulatory & Clinical Manager
560 Harrison Ave #403
BOSTON MA 02118

Re: K231678
Trade/Device Name: Overjet Periapical Radiolucency Assist
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical image analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: August 15, 2023
Received: August 15, 2023

Dear Deepthi Paknikar:

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

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
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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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K231678

Device Name
Overjet Periapical Radiolucency Assist

Indications for Use *(Describe)*
Overjet Periapical Radiolucency (PARL) Assist is a radiological, automated, concurrent read computer-assisted detection software intended to aid in the detection of periapical radiolucencies on permanent teeth captured on periapical radiographs. The device provides additional aid for the dentist to use in their identification of periapical radiolucency. The device is not intended as a replacement for a complete dentist's review or their clinical judgment that considers other relevant information from the image or patient history. The system is to be used by professionally trained and licensed dentists.

The Overjet Periapical Radiolucency Assist software is indicated for use on patients 12 years of age or older.

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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K231678

510(k) Summary

Prepared on: 2023-06-08

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Overjet, Inc
Applicant Address	560 Harrison Ave #403 Boston MA 02118 United States
Applicant Contact Telephone	6302011612
Applicant Contact	Deepthi Paknikar DDS, MS
Applicant Contact Email	deepthi.paknikar@overjet.ai

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Overjet Periapical Radiolucency Assist
Common Name	Medical image analyzer
Classification Name	Analyzer, Medical Image
Regulation Number	892.2070
Product Code	MYN

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221921	DTX Studio Clinic 3.0	MYN
K210365	Second Opinion®	MYN

Device Description Summary

21 CFR 807.92(a)(4)

Overjet Periapical Radiolucency "PARL" Assist is a module within the Overjet Platform. The Overjet PARL Assist (OPA) software automatically detects periapical radiolucency on periapical radiographs. It is intended to aid dentists in the detection of periapical radiolucency. 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 professionally trained and licensed dentists.

Overjet PARL Assist is a software-only device which operates in three layers: a Network Layer, a Presentation Layer, and a Decision Layer. Images are pulled in from a clinic/dental office, and the Machine Learning model creates predictions in the Decision Layer and results are pushed to the dashboard, which are in the Presentation Layer.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Overjet Periapical Radiolucency (PARL) Assist is a radiological, automated, concurrent read computer-assisted detection software intended to aid in the detection of periapical radiolucencies on permanent teeth captured on periapical radiographs. The device provides additional aid for the dentist to use in their identification of periapical radiolucency. The device is not intended as a replacement for a complete dentist's review or their clinical judgment that considers other relevant information from the image or patient history. The system is to be used by professionally trained and licensed dentists.

The Overjet Periapical Radiolucency Assist software is indicated for use on patients 12 years of age or older.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The minor differences between the Overjet PARL Assist subject device and the Primary Predicate Device DTX Studio Clinic 3.0 (K221921) and secondary predicate device Pearl Second opinion (K210365) do not constitute a new intended use. The Overjet PARL Assist device shares the same intended use as the primary and secondary predicates, and the device is intended to aid in the detection of PARL on 2D periapical radiographs. The primary predicate device is intended to be used for ages 15+ and the secondary predicate device is intended for ages 12+, same as the Overjet PARL Assist Device. The Overjet PARL Assist Device is a concurrent read device same as the primary predicate device. The primary predicate device outputs a toggleable bounding box whereas the Overjet device outputs a segmented polygon of PARL. Both devices are intended to be diagnostic aids, and provide information for clinicians to use as additional information in their clinical examinations. The performance testing for the Overjet PARL Assist device demonstrates that aided readers improve in detection of PARL over unaided readers. In summary, the Overjet PARL Assist Device is substantially equivalent to the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The primary predicate device outputs a toggleable bounding box whereas the Overjet device outputs a segmented polygon of PARL. The minor difference in technological characteristics do not raise a concern of substantial equivalence as demonstrated by the performance testing of the Overjet device.

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

MRMC Reader Study

Overjet evaluated the Overjet PARL Assist (OPA) in a multi reader multi case (MRMC) fully crossed reader improvement study. 19 US licensed dentists were asked to evaluate 379 periapical radiographs (190 images with at least 1 PARL and 189 images with no PARL). Images were obtained from male and female patients aged 12 years and older. The results were compared to the consensus reference standard established by 3 endodontists.

Half of the data set contained unassisted images (raw images not run on the OPA device), and the second half contained radiographs that had been "assisted" or processed through the OPA device. The radiographs were presented to the readers in alternating groups. A 4 week washout period was utilized to limit recollection bias. Following the washout, the readers were presented the same data set but with alternate grouping. This means that if a reader saw a radiograph in the unassisted state in Session 1, they were presented with the Overjet PARL Assist predictions in Session 2.

The results were compared against a consensus ground truth, and the area under the curve (AUC) of the receiver operating characteristic curve (ROC) was evaluated as a primary endpoint to characterize the performance of the readers assisted and unassisted by the Overjet PARL Assist device.

The AUC of the ROC at the image level averaged across all readers showed a 4.8 % (95% CI's 0.030, 0.066) improvement in assisted readers compared to unassisted readers. The p-value was highly statistically significant at <0.001.

Average Image level sensitivity across all readers increased by 13.6% (0.110, 0.165) when compared to unassisted readers. The average specificity at the image level decreased slightly from 83.2% to 76.1% (-0.071 difference, CI's (-0.099, -0.042)). Reader improvement for assisted readers at the instance (polygon) level sensitivity averaged across all readers was 16.2% (0.125, 0.194).

Standalone Performance Testing
Standalone performance of the Overjet PARL Assist device was evaluated for 763 periapical images (379 reader study images + 384 additional standalone study images). The dataset was split with 326 images with PARL and 437 images with no PARL. Images were obtained from male and female patients aged 12 years and older from various clinical sites across the U.S.. The results were compared to the consensus reference standard established by 3 endodontists.
Image level standalone sensitivity was 88%, 95% CI's (0.847, 0.914). Image Level standalone specificity was 84.2%, 95% CI's (0.810, 0.847). Polygon (instance) level standalone sensitivity was 66.4%, 95% CI's (0.615, 0.711).

Image Level Standalone Sensitivity and Specificity by sensor category is as follows:
Dexis - Sensitivity: 0.867 (0.800, 0.933) Specificity: 0.885 (0.827, 0.942)
e2v - Sensitivity: 0.861 (0.785, 0.937) Specificity: 0.804 (0.728, 0.875)
Gendex - Sensitivity: 0.889 (0.815, 0.951) Specificity: 0.793 (0.712, 0.865)
Schick - Sensitivity: 0.908 (0.836, 0.961) Specificity: 0.891 (0.827, 0.945)

Not Applicable - the 2 types of device performance testing in this submission include standalone and MRMC performance testing as described in the guidance documents "Computer-Assisted Detection Devices
Applied to Radiology Images and Radiology Device Data - Premarket Notification [510(k)] Submissions" and
"Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data in Premarket Notification (510(k)) Submissions".

The results of the MRMC reader performance assessment demonstrates that readers assisted by the Overjet PARL Assist device improve in detection of PARL when compared to unassisted readers.