March 4, 2024

Overjet, Inc
% Deepthi Paknikar
Senior Manager, Regulatory and Clinical Affairs
50 Milk Street, 16th Floor
BOSTON, MA 02109

Re: K233738
Trade/Device Name: Overjet Caries Assist-Pediatric
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical Image Analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: February 2, 2024
Received: February 2, 2024

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 (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
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
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OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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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)*
K233738

Device Name

Overjet Caries Assist-Pediatric

Indications for Use *(Describe)*
Overjet Caries Assist-Pediatric (OCA-Ped) is a radiological, automated, concurrent-read, computer-assisted detection (CADe) software intended to aid in the detection and segmentation of caries on bitewing and periapical radiographs. The device provides additional information for the clinician to use in their diagnosis of a tooth surface suspected of being carious. The device is not intended as a replacement for a complete dentist's review or their clinical judgment that takes into account other relevant information from the image, patient history, or actual in vivo clinical assessment.

The intended patient population of the device is patients aged 4-11 years old that have primary or permanent teeth (primary or mixed dentition) and are indicated for dental radiographs.

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.

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K233738

Applicant Name: Overjet, Inc
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Device Trade Name: Overjet Caries Assist-Pediatric
Classification Name: Medical image analyzer
Common Name: Analyzer, Medical Image
Regulation Number: 892.2070
Product Code: MYN

Legally Marketed Predicate Device: Overjet Caries Assist
Predicate Product Code: MYN
Predicate K number: K222746

Device Description Summary

Overjet Caries Assist-Pediatric (OCA-Ped) is a radiological, automated, concurrent-read, computer-assisted
detection (CADe) software intended to aid in the detection and segmentation of caries on bitewing and periapical radiographs. The device provides additional information for the dentist to use in their diagnosis of a tooth surface suspected of being carious. The device is not intended as a replacement for a complete dentist's review or their clinical judgment that takes into account other relevant information from the image, patient history, or actual in vivo clinical assessment.

OCA-Ped 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

Overjet Caries Assist-Pediatric (OCA-Ped) is a radiological, automated, concurrent-read, computer-assisted detection (CADe) software intended to aid in the detection and segmentation of caries

on bitewing and periapical radiographs. The device provides additional information for the clinician to use in their diagnosis of a tooth surface suspected of being carious. The device is not intended as a replacement for a complete dentist's review or their clinical judgment that takes into account other relevant information from the image, patient history, or actual in vivo clinical assessment.

The intended patient population of the device is patients aged 4-11 years old that have primary or permanent teeth (primary or mixed dentition) and are indicated for dental radiographs.

Indications for Use Comparison

The minor differences between the Overjet Caries Assist-Pediatric "OCA-Ped" subject device and the Primary Predicate Device Overjet Caries Assist "OCA" (K222746) do not constitute a new intended use. The OCA-Ped device shares the same intended use as the primary predicate, and the device is intended to aid in the detection of caries on 2D bitewing and periapical radiographs. The primary predicate device is intended to be used for patients with permanent teeth, ages 12+. The subject OCA-Ped device is intended to be used for patients with permanent and primary teeth (primary or mixed dentition) ages 4-11. The OCA-Ped device is a concurrent read device same as the primary predicate device. The primary predicate device outputs a polygon annotation in areas of suspected caries, that can be adjusted, hidden, deleted, and viewed with or without a color fill. The subject device has the same output and same adjustable features for the user. Both devices are intended to be diagnostic aids, and provide information for clinicians to use as additional information in their clinical examinations. Both devices are not intended to replace a complete review and clinical judgment of a clinician. The performance testing for the Overjet Caries Assist-Pediatric device demonstrates that aided readers improve in detection of caries over unaided readers.

Technological Comparison

There are no differences in technological characteristics that raise a concern of substantial equivalence as demonstrated by the performance and software testing of the Overjet Caries Assist-Pediatric device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

MRMC Reader Study

Overjet evaluated the Overjet Caries Assist-Pediatric "OCA-Ped" in a multi reader multi case (MRMC) fully crossed reader improvement study. 20 US licensed dentists were asked to evaluate 636 images, each from a unique patient. Roughly half the images had caries, and half without. Images were obtained from male and female patients aged 4-11 years. The results were compared to the consensus reference standard established by 3 general dentists.
Half of the data set contained unassisted images (raw images not run on the OCA-Ped device), and the second half contained radiographs that had been "assisted" or processed through the OCA-Ped device. The radiographs were presented to the readers in alternating groups. A 4 week washout period was utilized between two sessions to limit recollection bias. Following the washout, the readers were presented the same data set but with alternate grouping.

The results were compared against a consensus ground truth, and the area under the curve (AUC) of the wAFROC was evaluated as a primary endpoint to characterize the performance of the readers assisted and unassisted by the Overjet Caries Assist-Pediatric device.

The AUC of the wAFROC averaged across all readers showed a 7.5% improvement, with 95% CI's (0.062, 0.088) in assisted readers compared to unassisted readers. The p-value was highly statistically significant.

Average Tooth level sensitivity across all readers increased by 11.8% (0.102, 0.137) when compared to unassisted readers. The average specificity at the tooth level decreased slightly with a difference of -0.011 (-0.015, -0.008) between the assisted and unassisted readers.

Standalone Performance Testing

Standalone performance of the Overjet Caries Assist-Pediatric device was evaluated for 1190 bitewing and periapical images. The dataset was split with roughly 50-50 images with and without caries, for patients aged 4-11. Images were obtained from male and female patients, from a range of distinctly different geographic regions. The results were compared to the consensus reference standard established by 3 general dentists.
Tooth level standalone sensitivity was 83.9%, 95% CI's (0.816, 0.860).
Tooth Level standalone specificity was 97.5%, 95% CI's (0.971, 0.979).
Standalone Dice was a mean of 79.0%, 95% CI's (0.784, 0.797).

Tooth Level Standalone Sensitivity with 95% CI's by sensor category is as follows:
Carestream 0.870 (0.832, 0.900)
Dexis 0.872 (0.841, 0.902)
E2V 0.761 (0.713, 0.806)
Gendex 0.843 (0.800, 0.882)
Schick 0.844 (0.805, 0.878)

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 Caries Assist-Pediatric device improve in detection of caries when compared to unassisted readers.