March 27, 2023

Overjet, Inc.
% Adam Odeh
Director, Regulatory Affairs and Quality Assurance
560 Harrison St., Unit 403
BOSTON, MA 02118

Re: K222746
Trade/Device Name: Overjet Caries Assist
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical Image Analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: February 23, 2023
Received: February 23, 2023

Dear Adam Odeh:

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 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)*
K222746

Device Name
Overjet Caries Assist

Indications for Use *(Describe)*
Overjet Caries Assist (OCA) 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.

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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510(k) Summary

(K222746)

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

1. **Date**

   11 Sep 2022

2. **Applicant**

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

3. **Trade Name**

   Overjet Caries Assist

4. **Common Name**

   Medical Image Analyzer

5. **Classification**

   21 CFR 892.2070, Product code MYN, Class 2, Radiology

6. **Device Description**

   Overjet Caries Assist (OCA) 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 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.

   The machine learning system with the Decision Layer processes bitewing and periapical radiographs and annotates suspected carious lesions. It is comprised of four modules:

   - *Image Preprocessor Module* - This module performs two functions:

    - Resizes and normalizes the images
    - Evaluates the incoming radiograph and predicts the image type as Bitewing, Periapical, or other. Any images classified as "other" are not processed.

- *Tooth Number Assignment Module* - This module analyzes the processed image and determines what tooth numbers are present and provides a pixel wise segmentation mask for each tooth number.
- *Caries Module* - This model segments carious lesions using an ensemble of 3 Instance Segmentation models.
- *Post Processing* - The overlap of tooth masks from the *Tooth Number Assignment Module* and carious lesions from the *Caries Module* are used to assign specific carious lesions to a specific tooth. The Post Processing module annotates the original radiograph with the carious lesions' predictions.

7. Indications for Use

Overjet Caries Assist (OCA) 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.

8. Intended Patient Population

The intended patient population of the device is patients that have permanent dentition, and who are at least 12 years of age.

9. Warnings and Limitations

- The safety and effectiveness of the system has not been established on primary or mixed dentition.
- The device should only be used by licensed dentists.
- The Overjet Caries Assist device assists only in potential caries detection, and should not be relied upon as the sole decision-making tool for diagnosis or treatment.
- Overjet Caries Assist has been tested with the sensors listed here and in the user manual. Overjet cannot guarantee the accuracy of results when Overjet Caries Assist is used on images from other sensors.
- The Overjet Caries Assist device is not intended for images smaller than 500 x 500 resolution. Overjet cannot guarantee the accuracy of results when Overjet Caries Assist is used on images of lower resolution.
- If images are rotated incorrectly (i.e., left side bitewing on right side), tooth numbering and caries predictions will not be accurate.
- As with any CADe device, the product has the potential for false positive or false negative outputs. The user should use all appropriate clinical information to render a final clinical opinion, with radiographic interpretation assisted by Overjet being one component of the determination process.
- The Overjet Caries Assist device is trained to detect caries based on radiolucencies visible on radiographs. In areas where teeth overlap significantly, Overjet Caries Assist is trained to not predict caries due to the high potential of detecting false positives. If tooth overlap is present but the radiolucency can still be distinctly visualized, Overjet Caries Assist will predict in these areas.

10. Predicate Device/Device to be Modified

Device: Overjet Caries Assist

Manufacturer - Overjet, Inc.

Previously cleared as K212519

10. Substantial Equivalence

Device	Overjet Caries Assist (Predicate)	Overjet Caries Assist (Proposed)
510k	K212519	TBD
Regulation No / Description	CFR 892.2070 Medical image analyzer	CFR 892.2070 Medical image analyzer
Indications	The Overjet Caries Assist is a radiological, automated, concurrent read, computer-assisted detection software intended to aid in the detection and segmentation of caries on bitewing 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.	Overjet Caries Assist (OCA) 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.
Type of CAD	CADe	CADe
End User	Dentist	Dentist
Patient Population	Patients requiring dental services, all sexes, 18 years of age or older	Patients requiring dental services, all sexes, **12 years of age or older with permanent teeth**
Platform	Web - Edge, Chrome, Firefox	Web - Edge, Chrome, Firefox
OS	Any	Any
User Interface	Mouse, Keyboard, Trackpad	Mouse, Keyboard, Trackpad
Image Input Sources	Images imported from the radiographic device, or from the practice management system, from Carestream or Schick sensors.	Images imported from the radiographic device, or from the practice management system **from multiple sensor manufacturers**
Image format	jpg, png, eop, jif, dicom	jpg, png, eop, tiff, dicom

Device	Overjet Caries Assist (Predicate)	Overjet Caries Assist (Proposed)
Processing Architecture	Three layers: 1 - The Network layer works with the practice PACS or EMR to transmit the image and meta-data to Overjet. 2 - The decision layer processes the image to ensure it is the correct data type, and then annotates it via the algorithm 3 - The presentation layer displays the annotated image in a non-diagnostic viewer. The dentist can filter, display, hide, create and edit the annotations presented.	Three layers: 1 - The Network layer works with the practice PACS or EMR to transmit the image and meta-data to Overjet. 2 - The decision layer processes the image to ensure it is the correct data type, and then annotates it via the algorithm 3 - The presentation layer displays the annotated image in a non-diagnostic viewer. The dentist can filter, display, hide, create and edit the annotations presented.
Data Source	Digital files of bitewing radiographs whose longer edge is greater than 500 pixel resolution.	Digital files of bitewing **and periapical** radiographs whose longer edge is greater than 500 pixel resolution.
Output	Caries detection and segmentation on radiograph resulting in outline of suspected caries	Caries detection and segmentation on radiograph resulting in outline **or fill** of suspected caries
Performance Testing	Increase in dentist's sensitivity of greater than 15%	Increase in dentist's sensitivity of greater than 15%
Level of Concern	Moderate	Moderate

The subject Overjet Caries Assist (OCA) device for this 510k submission is determined to be substantially equivalent to the previously cleared OCA device (K212519). The differences are as follows:

- Analysis of Periapical radiographs in addition to Bitewing radiographs
- Multiple sensor manufacturers, as opposed to previous clearance for only two sensor manufacturers
- Target population is 12 years and older with permanent teeth (as opposed to 18 years and older, in K212519)

Overjet does not believe that these differences raise any concerns of substantial equivalence, and that the changes to intended use are well supported by performance testing and present no increased risk to patients.

11. Performance Testing

Overjet has conducted performance testing according to FDA's "Guidance for Industry and Food and Drug Administration Staff Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Notification [510(k)] Submissions Document" issued on 03 Jul 2012 and the "Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data in Premarket Notification (510(k)) Submissions" Guidance issued January 2020, as part of the development process of the caries model. Performance testing included standalone testing and a clinical reader evaluation. All testing demonstrated that Overjet Caries Assist (OCA) met prespecified requirements.

Standalone Testing

Standalone performance of the Overjet AI algorithm was evaluated on a total of 1,293 Bitewing images and 1,314 Periapical images. Sensitivity and specificity were summarized based on surfaces, and 95% CIs were provided based on treating the subject as the basis of a cluster. A total of 27,920 bitewing surfaces and 16,254 periapical surfaces were available and included in the analysis. Standalone performance of the OCA device was compared to a ground truth established by consensus of labels of three US licensed dentists, and non-consensus labels were adjudicated by an oral radiologist.

Standalone testing included images from the following sensor manufacturers: Carestream, Dexis, e2v, Gendex, Hamamatsu, Jazz Imaging, ScanX, Schick, Soredex Digora.

Sensitivity

For bitewing images, overall standalone sensitivity was **76.6%** (73.8%, 79.4%). Subgroup sensitivity was as follows: Primary caries - **79.9%** (77.1%, 82.7%); Secondary caries - **60.9%** (53.5%, 68.2%); Enamel - **74.4%** (70.4%, 78.3%); Dentin - **79.5%** (75.8%, 83.2%)

For periapical images, overall standalone sensitivity was **79.4%** (76.1%, 82.8%). Subgroup sensitivity was as follows: Primary caries - **79.8%** (76.0%, 83.7%); Secondary caries - **77.9%** (71.4%, 84.5%); Enamel - **67.9%** (60.7%, 75.1%); Dentin - **84.9%** (81.3%, 88.4%).

Specificity

Overall specificity was **99.1%** (98.9%, 99.2%) for bitewing images, and **99.4%** (99.2%, 99.5%) for periapical images.

Subgroup Analyses

Subgroup analyses were also performed for age, sex, sensor, and associated restoration (for secondary caries).

Lesion Segmentation

Dice coefficient analysis was performed to compare pixel-level metrics of each carious lesion with the lesion tracing provided by ground truthers. Dice scores were calculated only for true positives.

For bitewing images, the mean Dice score was **0.77** (0.76, 0.78) for primary caries, **0.73** (0.70, 0.75) for secondary caries, **0.76** (0.75, 0.77) for enamel caries, and **0.77** (0.76, 0.79) for dentin caries.

For periapical images, the mean Dice score was **0.79** (0.78, 0.81) for primary caries, **0.79** (0.77, 0.82) for secondary caries, **0.75** (0.73, 0.77) for enamel caries, and **0.81** (0.80, 0.82) for dentin caries.

Clinical Evaluation - Reader Improvement

Overjet evaluated the performance of Overjet Caries Assist in a multi-reader fully crossed reader improvement study. 28 US licensed dentists were split into 2 groups of 14 each. One group was asked to evaluate 330 bitewing images (94 containing caries / 236 without caries) and the other was asked to evaluate 330 periapical images (also 94 containing caries / 236 without caries). Ground truth was established by the consensus labels of three US licensed dentists, and non-consensus labels were adjudicated by an oral radiologist. Half of the data set contained unannotated images, and the second half contained radiographs that had been processed through the OCA model. Radiographs were presented to readers in alternating groups.

In Session 1, readers were asked to outline suspected caries, and to review predictions from the OCA model. Each reader was asked to provide a rating of 1 - 4 for their confidence in the annotation (1 for lowest confidence, up to 4 for highest confidence). 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. I.e., if a reader saw a radiograph in the unpredicted state in session 1, they were presented with the same radiograph with OCA predictions in session 2, and vice versa.

Results were compared against a consensus ground truth, and the sensitivity, specificity, and weighted alternative free response receiver operating characteristic (wAFROC) were evaluated to characterize the performance of the readers with (assisted) and without (unassisted) viewing the model annotations.

Unassisted vs. Assisted Sensitivity:

For bitewing images, overall reader sensitivity improved from **64.6%** (56.4%, 72.1%) to **78.5%** (72.6%, 83.6%) unassisted vs assisted. Subgroup improvement was as follows:
Primary caries - **67.1%** (58.3%, 74.8%) to **83.1%** (78.0%, 87.7%)
Secondary caries - **51.2%** (35.9%, 66.1%) to **55.8%** (40.9%, 70.4%)
Enamel - **61.8%** (51.5%, 71.0%) to **77.6%** (70.1%, 83.9%)
Dentin - **68.5%** (59.8%, 76.8%) to **79.9%** (72.6%, 86.9%)

For periapical images, overall reader sensitivity improved from **65.6%** (59.4%, 71.7%) to **79.0%** (73.0%, 84.7%) unassisted vs assisted. Subgroup improvement was as follows:

Primary caries - **67.5%** (60.8%, 74.1%) to **80.5%** (73.6%, 86.8%)

Secondary caries - **56.1%** (43.5%, 69.3%) to **71.6%** (59.1%, 83.5%)

Enamel - **58.6%** (47.2%, 69.4%) to **74.1%** (63.9%, 83.2%)

Dentin - **69.6%** (62.5%, 76.0%) to **81.9%** (75.1%, 88.3%)

Unassisted vs. Assisted Specificity:

For bitewing images, overall reader specificity decreased slightly from **99.0%** (98.5%, 99.4%) to **98.6%** (98.0%, 99.0%) unassisted vs assisted.

For periapical images, overall reader specificity decreased slightly from **98.0%** (97.4%, 98.6%) to **97.6%** (97.0%, 98.1%) unassisted vs assisted.

Subgroup Analyses:

Subgroup analyses were also performed for age, gender, sensor, reader experience, and associated restoration (for secondary caries).

Unassisted vs Assisted Dice Scores:

As with standalone testing, Dice scores were calculated in comparison to ground truth for readers with and without Overjet Caries Assist.

On bitewing images, mean Dice scores increased from **0.67** (0.009 SD) to **0.76** (0.009 SD) for primary caries, **0.65** (0.017 SD) to **0.67** (0.016 SD) for secondary caries, **0.65** (0.009 SD) to **0.74** (0.009 SD) for enamel, and **0.67** (0.012 SD) to **0.74** (0.012 SD) for dentin.

On periapical images, mean Dice scores increased from **0.73** (0.011 SD) to **0.80** (0.011 SD) for primary caries, **0.69** (0.025 SD) to **0.74** (0.025 SD) for secondary caries, **0.64** (0.015 SD) to **0.73** (0.014 SD) for enamel, and **0.76** (0.013 SD) to **0.81** (0.013 SD) for dentin.

Weighted AFROC (wAFROC) Scores:

Readers provided confidence scores for any detected caries, which were used to calculate AUC for weighted AFROC scores.

On bitewing images, for the average of all readers, AUC increased from **0.729** (0.696, 0.761) to **0.785** (0.746, 0.822), for an increase in AUC of **0.055** (0.033, 0.079) unassisted to assisted. This increase was statistically significant, with an overall p-value less than 0.001.

On periapical images, for the average of all readers, AUC increased from **0.799** (0.764, 0.833) to **0.848** (0.814, 0.881), for an increase in AUC of **0.050** (0.031, 0.068) unassisted to assisted. This increase was also statistically significant, with an overall p-value less than 0.001.

Summary

Increase in overall wAFROC numbers clearly demonstrate improvement in caries detection by dentists when aided by Overjet Caries Assist (0.055 increase for bitewing, 0.050 increase for periapical). This aligns with the observed increases in sensitivity for both bitewing and periapical images. When considered alongside the decreases in overall specificity (only 0.4% for both bitewing and periapical images), it is clear that Overjet Caries Assist demonstrates a clear benefit for caries detection.

12. **General Safety and Effectiveness Concerns**

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of this device. Risk management was conducted according to ISO 14971, which ensured, via a risk analysis, the identification and mitigation of potential hazards. Any potential hazards were controlled via software development and design, verification, and validation testing. In addition, general and special controls of the FD&C Act established for Radiological Computer Assisted Detection and Diagnosis Software are in place to further mitigate any safety and or effectiveness risks.

13. **Assessment of Non-clinical Performance Data**

Overjet Caries Assist has been verified and validated according to Overjet's design control processes. All supporting documentation has been included in this 510(k) premarket notification. Verification activity included unit, integration, and system level testing. Validation testing included performing a pivotal reader study to compare the clinical performance of dentists using CAD detections from Overjet Caries Assist software when applied to dental radiographs to that of dentists not using Overjet Caries Assist.

14. Conclusion

The subject device Overjet Caries Assist (OCA) is substantially equivalent to the predicate OCA device. Differences do not raise any concerns about the safety or efficacy of the device.