May 10, 2022

Overjet, Inc.
% Adam Odeh
Regulatory Contact
560 Harrison Ave, Unit 403
BOSTON MA 02118

Re: K212519
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: April 6, 2022
Received: April 7, 2022

Dear Mr. 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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT 8B: Division of Radiological Imaging
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)*
K212519

Device Name
Overjet Caries Assist

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

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 4: 510(k) Summary (K212519)

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

1. Date Prepared: October 19, 2021

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 Imaging 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 (CAD) software intended to aid in the detection and segmentation of caries on bitewing 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 clinician's review or their clinical judgment that takes into account other relevant information from the image or patient history.

OCA is a software-only device which operates in three layers – a Network Layer, a Presentation Layer, and a Decision Layer (as shown in the data flow diagram below). 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 within the Decision Layer processes bitewing radiographs and annotates suspected carious lesions. It is comprised of four modules:

- *Image Classifier* - The model evaluates the incoming radiograph and predicts the image type between Bitewing and Periapical Radiograph. This classification is

used to support the data flow of the incoming radiograph. As part of the classification of the image type any non-radiographs are classified as "junk" and not processed. These include patient charting information, or other non-bitewing or periapical radiographs. OCA shares classifier and Tooth Number modules with the Overjet Dental Assist product cleared under K210187.

- *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 module outputs a pixel wise segmentation mask of all carious lesions using an ensemble of 3 U-Net based models. The shape and location of every carious lesion is contained in this mask as the carious lesions' predictions.

- *Post Processing* - The overlap of tooth masks from the *Tooth Number Assignment Module* and carious lesions from the *Caries Module* is used to assign specific carious lesions to a specific tooth. The Image Post Processor module annotates the original radiograph with the carious lesions' predictions.

7. Indications for Use

   The Overjet Caries Assist (OCA) 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, and actual in vivo clinical assessment.

8. Intended Patient Population:

   The intended patient population of the device is patients that have permanent dentition, and are at least 18 years of age.

9. Warning and Limitations:

   - The safety and effectiveness of the system has not been established in patients with primary or mixed dentition.
   - The device should only be used by trained dentists.
   - Overjet Caries Assist system assists only in potential caries detection, not interpretation or diagnosis. It should not be relied on as the sole decision-making tool for diagnosis or treatment.
   - Only images from a supported dental radiograph system as defined in the manual can be

used.

- The Overjet Dental Assist system 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.
- The product is not 100% sensitive, and some caries will not be detected. This can delay necessary treatment.
- Gross decay detection is not supported by Overjet Caries Assist, as the algorithm has been trained to detect caries within the tooth structure, rather than to detect a lack of tooth structure as is often observed with severe decay.
- Endodontic access may be mistaken by the product as caries, due to the similarities on the radiographs.
- Overjet Caries Assist cannot detect carious lesions that are not visible to a dentist on bitewing radiographs (e.g., obstructed by radiopaque restorations).
- The product has the potential for false positive or false negative outputs. This could result in unnecessary treatment on rare occasions. Final clinical determination is the responsibility of the treating clinician with the assessment of the actual patient's dentition and multiple clinical indicators of treatment unrelated to the prediction.
- The dentist should use all appropriate clinical information to render a final clinical opinion, with radiographic interpretation being one component of the determination process.
- The dentist is responsible for reviewing the segmentation accuracy prior to making diagnostic decisions, and for manually adjusting segmentation when deemed necessary.

10. Predicate Device

Device - Logicon Caries Detector
Manufacturer - Carestream Dental
PMA - P980025 (down-classified to Class II under 85 FR 3548, Jan. 22, 2020)

9. Substantial Equivalence

Device	Carestream Logicon Caries Detector	Overjet Caries Assist (proposed)
510k	P980025	K212519
Regulation No. / Description	CFR 892.2070 Medical image analyzer	CFR 892.2070 Medical image analyzer
Indications	The Logicon Caries Detector is a software device that is an aid in the diagnosis of caries that have penetrated into the dentin, on un-restored proximal surfaces of secondary dentition through the statistical analysis of digital intra-oral radiographic imagery. The device provides additional information for the clinician to use in his/her diagnosis of a tooth surface suspected of being carious. It is designed to work in conjunction with an existing Carestream dental RVG digital X-ray radiographic system with dental imaging software (dis) for Windows XP or higher.	The Overjet Caries Assist (OCA) 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, and actual in vivo clinical assessment.
End User	Dentist	Dentist
Patient Population	Patients requiring dental services, all sexes, no age restriction	Patients requiring dental services, all sexes, at least 18 years of age, and with permanent dentition.
Platform	Windows PC	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 connected Carestream image solutions	Images imported from the radiographic device, or from the practice management system, from Carestream or Schick sensors
Image format	Carestream	jpg, png, eop, jif, dicom

Processing Architecture	The software provides graphical representation of the density change in a tooth, by looking for a pattern of density dips starting at the tooth surface, penetrating the enamel and going into the dentin. Enamel is represented by 10 green lines and dentin by 5 blue lines. If a pattern suggestive of caries exists, the dips are highlighted with red dots to warn the dentist.	Three layers: - The Network layer works with the practice PACS or EMR to transmit the image and meta-data to Overjet. - The decision layer processes the image to ensure it is the correct data type, and then annotates it via the algorithm - 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	Bitewing radiographs acquired from Carestream dental RVG digital X-ray radiographic system	Digital files of Bitewing radiographs whose longer edge is greater than 500 pixel resolution
Output	● Outline of suspected region ● Tooth Density ● Lesion (caries) probability	Caries detection and segmentation on radiograph resulting in outline of suspected caries
Performance Testing	Increase in dentist's sensitivity of approximately 20%	Increase in dentist's sensitivity of greater than 15%
Level of Concern	Moderate	Moderate

Overjet Caries Assist is determined to be substantially equivalent to the Carestream Logicon Caries Detector approved in P980025 and later down-classified to Class II under 85 FR 3548, Jan. 22, 2020. Both systems are software intended to support dental professionals in their diagnosis and treatment planning for caries.

Both software systems automatically annotate suspected carious lesions for the dentist to review. The Logicon software displays suspected carious lesions as dips in annotated lines within the radiograph, green lines for the enamel and blue lines for the dentin. The Overjet Caries Assist presents suspected carious lesions as segmented polygons outlining the prediction. 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. Logicon compatibility is limited to Carestream products

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 Carestream

Logicon is a local software while Overjet Caries Assist is a cloud native application. While Logicon and Overjet Caries Assist have different user interfaces, both are accessed by computer and are intended for dental professionals to review annotations on dental radiographs. Overjet does not believe 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

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: July 3, 2012, as part of the development process of the caries model. Performance testing included standalone testing and a clinical reader evaluation. All testing demonstrated that the Overjet Caries Assist software met prespecified requirements.

Standalone Testing

Standalone performance of the Overjet AI algorithm for the 352 images is shown in the tables below. 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 7,129 surfaces were available and included in the analysis.

Sensitivity

Overall standalone sensitivity was **72.0%** (62.9%, 81.1%). When broken down further, sensitivity was **74.4%** (64.4%, 84.4%) for primary caries, and **62.5%** (46.6%, 78.4%) for secondary caries.

Specificity

Overall standalone specificity was **98.1%** (97.7%, 98.5%).

Subgroup Analyses:

Subgroup analyses were also performed for age, gender, and sensor, as well as by primary vs secondary classification, and associated restoration (for secondary caries).

Standalone Performance of Overjet AI Algorithm based on Surfaces

		Ground Truth		
Assessment	**Overjet AI**	**Caries Present**	**No Caries Present**	**Total (%)**
Observed Counts	Caries Present No Caries Total (%)	175 (2.5%) 68 (1.0%) 243 (3.4%)	131 (1.8%) 6755 (94.8%) 6886 (96.6%)	306 (4.3%) 6823 (95.7%) 7129
Diagnostic Statistic	Measure Sensitivity Specificity	Estimate 72.0% (175/243) 98.1% (6755/6886)	95% CI[1] 62.9%, 81.1% 97.7%, 98.5%	

[1] Confidence interval adjusted for multiple images and caries per subject based on clustered binary data methodology.

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 66 images containing primary caries, the mean Dice score was **0.69** (0.66, 0.72) with a standard deviation of 0.122). For 30 images containing secondary caries, the mean Dice score was **0.75** (0.71, 0.79) with a standard deviation of 0.112.

Thus, it is unlikely that the automatic lesion segmentation presents any new risks, and any such potential risks are mitigated by the fact that Overjet Caries Assist allows the dentist to modify the margins of any segmented lesions.

Clinical Evaluation - Reader Improvement

Overjet evaluated the Overjet Caries Assist in a multi reader fully crossed reader improvement study. 13 US licensed dentists were asked to evaluate 352 radiographs (104 containing caries / 248 without caries). Ground truth was established by the consensus labels of three US licensed dentists, and non-consensus labels were adjudicated by a Dental Radiologist. Half of the data set contained unannotated images, and the second half contained radiographs that had been processed through the OCA model. The radiographs were presented to the reader in alternating groups.

In Session 1, the 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 label (1 low confidence, 4 high confidence). A 30-day washout period was utilized to limit recollection bias. Following the washout, the readers were presented the same data set but with alternate grouping. If a reader saw a radiograph in the unpredicted state in session 1, they were presented with the Overjet Caries Assist

predictions in session 2.

The results were compared against a consensus ground truth, and the sensitivity, specificity, and alternative free response receiver operating characteristic (AFROC) was evaluated to characterize the performance of the readers with and without viewing the model annotations.

Unassisted vs Assisted Sensitivity:

Overall reader sensitivity improved from **57.9%** (48.9%, 66.0%) to **76.2%** (68.4%, 82.6%) unassisted vs assisted. For primary caries, reader sensitivity improved from **60.5%** (49.3%, 69.2%) to **79.4%** (71.0%, 85.9%). For secondary caries, reader sensitivity improved from **49.8%** (39.5%, 60.6%) to **63.0%** (52.0%, 74.8%).

Unassisted vs Assisted Specificity:

Overall reader specificity decreased slightly from **99.3%** (99.1%, 99.5%) to **98.4%** (94.5%, 98.8%) unassisted vs assisted.

Subgroup Analyses:

Subgroup analyses were performed for age, gender, and sensor, primary vs secondary classification, 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.

For primary caries, mean Dice scores improved from **0.67** unassisted (standard deviation 0.012) to **0.69** assisted (SD 0.011). For secondary caries, mean Dice scores improved from **0.65** unassisted (SD 0.017) to **0.74** assisted (SD 0.017). These data suggest improved segmentation when using Overjet Caries Assist, though results were not statistically significant.

AFROC Scores:

Readers provided confidence scores for any detected caries, which were used to calculate AUC for weighted AFROC scores. For the average of all readers, AUC increased from **0.593** (0.686, 0.743) to **0.649** (0.744, 0.820), for an increase in AUC of **0.057** (0.039, 0.098) unassisted to assisted. This increase was statistically significant, with an overall p-value less than 0.001.

Summary

Increases in overall AFROC numbers clearly demonstrate improvement in caries detection by dentists when aided by Overjet Caries Assist (0.057 increase). This aligns with the observed increase in sensitivity for both primary and secondary caries (18.9% improvement for primary; 13.2% improvement for secondary caries). When considered alongside the observed decrease in overall specificity, which was less than 1%, it is clear that Overjet Caries Assist demonstrates a clear benefit for caries detection.

11. 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.

12. 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 the Overjet Caries Assist software when applied to dental radiographs to that of dentists not using Overjet Caries Assist.

13. Conclusion

Overjet Caries Assist is substantially equivalent to the predicate device, Carestream Logicon Caries Detector. Any differences do not raise any concerns about the safety or efficacy of the device.