December 16, 2022

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

Re: K220928
Trade/Device Name: Overjet Calculus Assist
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical Image Analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: November 15, 2022
Received: November 17, 2022

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 2022.12.16 14:56:46 -05'00'

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT8B: Division of Radiological 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)*
K220928

Device Name
Overjet Calculus Assist

Indications for Use *(Describe)*
Overjet Calculus Assist (OCalA) is a radiological automated concurrent-read computer-assisted detection software intended to aid in the detection of interproximal calculus deposits on both bitewing and periapical radiographs. The Overjet Calculus Assist surrounds suspected calculus deposits with a bounding box. The device provides additional information for the dentist to use in their diagnosis of a tooth surface suspected of containing calculus deposits. 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 or patient history. The system is to be used by professionally trained and licensed dentists.

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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510(k) Summary

(K220928)

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

1. **Date Prepared**
   November 15, 2022

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

3. **Trade Name**
   Overjet Calculus Assist

4. **Common Name**
   Medical Image Analyzer

5. **Classification**
   21 CFR 892.2070, Product code MYN, Class 2, Radiology

6. **Device Description**
   Overjet Calculus Assist is a module within the Overjet Platform. The Overjet Calculus Assist (OCalA) software automatically detects interproximal calculus on bitewing and periapical radiographs. It is intended to aid dentists in the detection of calculus. 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.

7. **Indications for Use**
   Overjet Calculus Assist (OCalA) is a radiological automated concurrent-read computer-assisted detection software intended to aid in the detection of interproximal calculus deposits on both bitewing and periapical radiographs. The Overjet Calculus Assist surrounds suspected calculus deposits with a bounding box. The device provides additional information for the dentist to use in their diagnosis of a tooth surface suspected of containing calculus deposits. 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 or patient history. The system is to be used by professionally trained and licensed dentists.

8. Predicate Device

Device: Logicon Caries Detector
Manufacturer - Carestream Dental
PMA:P980025 (down-classified to class 2 under 85 FR 3548, Jan. 22, 2020)

9. Substantial Equivalence

Device	Carestream Logicon Caries Detector	Overjet Calculus Assist (proposed)
510k	P980025	K220928
Regulation No / Description	CFR 892.2070 Medical image analyzer	CFR 892.2070 Medical image analyzer
Intended Use	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 intraoral 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.	Overjet's Calculus Assist (OCalA) software automatically detects interproximal calculus on bitewing and periapical radiographs. It is intended to aid dentists in the detection of calculus. 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.
Type of CAD	CADe	CADe
End User	Dentist	Dentist
Patient Population	Patients requiring dental services, all sexes, no age restriction	Patients requiring dental services, all sexes, 18 years of age or older.
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
Image format		JPEG, PNG, JFIF, JIF, TIFF, EOP, BMP, 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: 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	Bitewing radiographs acquired from Carestream dental RVG digital X-ray radiographic system	Bitewing and periapical radiographs of at least 500 x 500 pixels.
Output	● Outline of suspected region ● Tooth Density ● Lesion (caries) probability	Calculus detection on radiograph resulting in bounding box outline of suspected calculus
Performance Testing	Increase in dentist's sensitivity of approximately 20%	Superiority of aided reader versus unaided reader performance
Level of Concern	Moderate	Moderate

Overjet Calculus Assist is determined to be substantially equivalent to the Carestream Logicon Caries Detector cleared as P980025. Both systems are software intended to support dental professionals in their diagnosis and treatment planning for their dental patients.

Both software systems automatically annotate suspected areas of interest 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 Calculus Assist presents suspected calculus deposits as bounding boxes 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 Calculus Assist is a cloud native application. While Logicon and Overjet Calculus 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 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

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

Standalone Testing

Standalone performance of the overjet AI algorithm for 296 bitewing radiographs and 322 periapical radiographs. 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 6,121 surfaces were available on bitewing radiographs, and 3,595 surfaces were available on periapical radiographs.

Sensitivity

Overall standalone sensitivity was **74.1%** (66.2%, 82.0%) for bitewing radiographs, and **72.9%** (65.3%, 80.5%) for periapical radiographs.

Specificity

Overall standalone specificity was **99.4%** (99.1%, 99.6%) for bitewing radiographs, and **99.6%** (99.3%, 99.8%) for periapical radiographs.

Subgroup Analyses

Subgroup analyses were also performed for age, gender, sensor, and clinical site. Results were generally similar across all subgroups, and any observed differences were not associated with increased risks.

AFROC

AFROC curves were derived using the polygon model scores associated with true positives and false positives for all areas identified on each image, which were used to generate and AFROC curve and associated AUC. Results are shown in the following table.

Image Type	AUC	95% CI[1]
Bitewing	0.859	0.823, 0.894
Periapical	0.867	0.828, 0.903
[1] Based on m=10000 bootstrap samples.		

Clinical Evaluation – Reader Improvement

Overjet evaluated the Overjet Calculus Assist in a multi-reader, fully crossed reader improvement study. 14 US licensed dentists were asked to evaluate 292 bitewing radiographs (85 with calculus and 211 without calculus) and 322 periapical radiographs (89 with calculus and 233 without calculus). 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 other half contained radiographs that had been processed through Overjet Calculus Assist. The radiographs were presented to the readers in alternating groups.

In Session 1, readers were asked to draw a box around suspected calculus, and to review predictions from the Overjet Calculus Assist 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 Calculus Assist predictions in session 2, and vice versa.

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

For bitewing radiographs, overall reader sensitivity improved from **74.9%** (68.3%, 80.2%) to **84.0%** (78.8%, 88.2%) unassisted vs assisted. For periapical radiographs, overall reader sensitivity improved from **74.7%** (69.9%, 79.0%) to **84.4%** (78.8%, 89.2%) unassisted vs assisted.

Unassisted vs. Assisted Specificity

For bitewing radiographs, overall reader specificity decreased slightly from **98.8%** (98.7%, 99.0%) to **98.6%** (98.4%, 98.9%) unassisted vs assisted. For periapical radiographs, overall

reader specificity also decreased slightly from **98.1%** (97.8%, 98.4%) to **98.0%** (97.7%, 98.4%) unassisted vs assisted.

Subgroup Analyses

Subgroup analyses were performed for age, gender, sensor, clinical site, and reader experience. While some differences were observed for various factors and interactions, reader improvement (unassisted vs assisted) was observed in nearly all analyses. No observed differences were associated with increased risks.

AFROC

Readers provided confidence scores for any detected calculus, which were used to calculate AUC for weighted AFROC scores. For the average of all readers, AUC increased from **0.840** (0.800, 0.880) to **0.878** (0.844, 0.913) on bitewing radiographs, and from **0.846** (0.808, 0.884) to **0.900** (0.870, 0.929) on periapical radiographs. Both increases were statistically significant.

Image Type	Modality	Reader Avg AUC of AFROC	StdError	95% CI	p-value on AUC Difference	Difference in AUCs	StdErr of Difference	95% CI on Difference
Bitewing	Assisted	0.878	0.017	0.844, 0.913	0.0055	0.038	0.013	0.012, 0.065
	Unassisted	0.840	0.020	0.800, 0.880				
Periapical	Assisted	0.900	0.015	0.870, 0.929	1.47e-05	0.054	0.011	0.032, 0.075
	Unassisted	0.846	0.019	0.808, 0.884				

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 Calculus 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 Calculus Assist software when applied to dental radiographs to

that of dentists not using Overjet Calculus Assist.

13. Conclusion

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