April 10, 2026

Overjet, Inc.
% Gayatri Sekaran
Head of Regulatory
200 State St.
Suite 1220
BOSTON, MA 02109

Re: K253930
Trade/Device Name: Overjet Iris Intelligent Imaging System
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: December 9, 2025
Received: March 16, 2026

Dear Gayatri Sekaran:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 Radiological Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253930

Please provide the device trade name(s).

Overjet Iris Intelligent Imaging System

Please provide your Indications for Use below.

Overjet Iris Intelligent Imaging System is a web-based dental image management software (Picture Archiving and Communication System, PACS). The system enables acquisition, cloud-based storage, archival, display, and distribution of digital dental images. Images can be acquired from dental image acquisition devices (intraoral sensors or extraoral panoramic machines) and/or consumer imaging devices such as color digital cameras.

In addition, the system provides automated identification and reporting of image capture quality issues, including the presence of intraoperative tools within the field of view, cone cut, overlapping interproximal contacts, inadequate crestal bone coverage, inadequate apical coverage, inadequate coronal coverage, foreshortening, and elongation. These image quality indicators are intended to assist clinicians in evaluating the adequacy of intraoral radiographs but are not a substitute for professional clinical judgment.

The device is intended to provide images for review and diagnostic use by trained dental professionals

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K253930 - 510(k) Summary

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

1. Date

April 08, 2026

2. Applicant

Overjet, Inc.
200 State St
Suite 1220
Boston, MA 02109
Contact Person: Gayatri Sekaran
Email: gayatri.sekaran@overjet.ai

3. Trade Name

Overjet Iris Intelligent Imaging System

4. Common Name

Automated Radiological Image Processing Software

5. Classification

Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product code: QIH
Review Panel: Radiology

6. Device Description

The Overjet Iris Intelligent Imaging System is a Medical Image Management and Processing System (MIMPS) device intended for use in dental practices. The system enables the acquisition, storage, display, and basic manipulation of digital dental images, including intraoral radiographs (bitewing, periapical), extraoral radiographs (panoramic), and intraoral/extraoral color photographs.

In addition to image capture and storage, the device incorporates AI/ML algorithms for image quality identification. These algorithms analyze bitewing and periapical radiographs immediately after acquisition and provide advisory indications of potential image quality

issues, including cone cuts, overlapping contacts, inadequate apical coverage, tube angulation errors etc.

7. Indications for Use

Overjet Iris Intelligent Imaging System is a web-based dental image management software (Picture Archiving and Communication System, PACS). The system enables acquisition, cloud-based storage, archival, display, and distribution of digital dental images. Images can be acquired from dental image acquisition devices (intraoral sensors or extraoral panoramic machines) and/or consumer imaging devices such as color digital cameras.

In addition, the system provides automated identification and reporting of image capture quality issues, including the presence of intraoperative tools within the field of view, cone cut, overlapping interproximal contacts, inadequate crestal bone coverage, inadequate apical coverage, inadequate coronal coverage, foreshortening, and elongation. These image quality indicators are intended to assist clinicians in evaluating the adequacy of intraoral radiographs but are not a substitute for professional clinical judgment.

The device is intended to provide images for review and diagnostic use by trained dental professionals

8. Predicate Device

Device:	VistaSoft 4.0 and VisionX 4.0
Manufacturer:	Durr Dental SE
Common Name:	Automated Radiological Image Processing Software
Regulation Number:	21 CFR 892.2050
Regulation Name:	Medical image management and processing system
Regulatory Class:	Class II
510(k) :	K250947
Product code:	QIH

9. Indications for Use Comparison:

The indications for Use for Iris Intelligent System is determined to be substantially equivalent to the predicate device. Both the Iris Intelligent Imaging System and the predicate VistaSoft 4.0 and VisionX 4.0 are medical image management systems intended to acquire, store, display, and support review of dental radiographs and related images by qualified dental professionals. Both devices share the same overall intended use and incorporate AI-based functions limited to assessing image quality.

The predicate device includes an AI-driven in-line image plate quality check to monitor plate degradation and recommends replacement, while the subject device provides a broader set of image capture quality indicators (e.g., cone cut, overlapping contacts, inadequate coverage, foreshortening, elongation, and intraoperative tools). This difference represents an expansion of quality check categories assessed but does not change the fundamental intended use, as neither device performs diagnosis or interpretation.

Overall, the differences do not raise new questions of safety and effectiveness, as both AI features are restricted to image quality assessment.

10. Technological Characteristics Comparison

Criteria	Subject Device Overjet Iris Intelligent Imaging System Overjet, Inc.	Primary Predicate VistaSoft 4.0 and VisionX 4.0 Durr Dental SE (K250947)	Comparison
Classification Regulation	21 CFR 892.2050, Medical Image Management and Processing System	21 CFR 892.2050, Medical Image Management and Processing System	Same
Intended Use/Indications for Use	Overjet Iris Intelligent Imaging System is a web-based dental image management software (Picture Archiving and Communication System, PACS). The system enables acquisition, cloud-based storage, archival, display, and distribution of digital dental images. Images can be acquired from dental image acquisition devices (intraoral sensors or extraoral panoramic machines) and/or consumer imaging devices such as color digital cameras. In addition, the system provides automated identification and reporting of image capture quality issues, including the presence of intraoperative tools within the field of view, cone cut, overlapping interproximal contacts, inadequate crestal bone coverage, inadequate apical coverage, inadequate coronal coverage, foreshortening, and elongation. These image quality indicators are intended to assist clinicians in evaluating the adequacy of intraoral radiographs but are not a substitute for professional clinical judgment. The device is intended to provide images for review and diagnostic use by trained dental professionals.	VistaSoft 4.0 and VisionX 4.0 imaging software is an image management system that allows dentists to acquire, display, edit, view, store, print, and distribute medical images. VisionX 4.0 / VistaSoft 4.0 runs on user provided PC compatible computers and utilize previously cleared digital image capture devices for image acquisition. The software must only be used by authorized healthcare professionals in dental areas for the following tasks: - Filter optimization of the display of 2D and 3D images for improved diagnosis - Acquisition, storage, management, display, analysis, editing and supporting diagnosis of digital/digitised 2D and 3D images and videos - Forwarding of images and additional data to external software (third-party software) The software is not intended for mammography use.	Both devices share the same overall intended use and incorporate AI-based functions limited to assessing image quality.
Host Platform	Web-application	PC-based application	The subject device uses web-application whereas the predicate uses PC-based application.

Criteria	Subject Device Overjet Iris Intelligent Imaging System Overjet, Inc.	Primary Predicate VistaSoft 4.0 and VisionX 4.0 Durr Dental SE (K250947)	Comparison
Image Type	2D dental images	2D and 3D dental images	The subject device is focused exclusively on 2D dental images while the predicate device uses 2D and 3D images.
Functions and Capabilities	● Browsing images by date and/or source ● Image viewer ● Uploading an Image file from the user's computer ● Acquiring an Image from a Web camera, TWAIN device and standard dental imaging devices (via integration with DICOM-compatible imaging application) ● Saving an Image to the local computer (via offline mode) ● Rotate Image (increments of 90 degrees) ● Flip Image Horizontally or Vertically ● Report image quality issues for intraoral radiographs (AI)	● Imaging application including a viewer and job interface ● Image viewer ● Acquiring images from video cameras, digital X-ray cameras, image plate scanners, extraoral X-ray devices, intraoral scanners and TWAIN compatible image sources. ● Saving and store images ● Automatic rotation (AI) ● Invert Image ● Automatic nerve canal tracing (AI) ● In-line automatic image plate quality checks (AI) ● Improved panoramic curve detection (AI) ● VistaSoft/VisionX Connect to integrate Dürr Dental and Air Techniques devices into 3rd party software	Both the subject and predicate device share substantially equivalent core features for acquiring, viewing, storing, and managing dental images, with similar basic image manipulation tools. The predicate provides AI-based in-line image plate quality checks and additional diagnostic support modules while the subject device instead provides AI-based reporting of image capture quality issues. The differences in scope of the features do not introduce new questions of safety or effectiveness.

The technological characteristics of the subject device are nearly identical to those of the predicate devices, with only minor feature differences. The subject device, Overjet Iris Intelligent Imaging System, and the predicate VistaSoft 4.0 and VisionX 4.0 share equivalent core features for acquiring, viewing, storing, and managing dental images, with similar basic image manipulation tools.

Both devices incorporate AI/ML algorithms limited to image quality functions. The predicate provides AI-based in-line image plate quality checks and additional diagnostic support modules (e.g., nerve canal tracing, panoramic curve detection), while the subject device instead provides AI-based reporting of image capture quality issues (e.g., cone cut, inadequate coverage, foreshortening, elongation etc.).

These differences do not raise new questions of safety or effectiveness, as both AI functionalities are restricted to image quality and not diagnosis or interpretation.

11. Performance Testing

Overjet conducted comprehensive nonclinical performance testing to support a determination of substantial equivalence for Overjet Iris Intelligent Imaging System. This included software verification and validation (V&V) testing in accordance with the FDA guidance 'Content of Premarket Submissions for Device Software Functions' (June 2023), and the FDA-recognized consensus standard IEC 62304:2006+A1:2015 for software lifecycle processes. Cybersecurity was evaluated in accordance with the FDA Guidance 'Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions' (June 2025). Testing encompassed unit-level validation, integration testing, system verification, and user acceptance testing, all of which confirmed that the software performs as intended under expected use conditions.

Standalone performance of the Overjet Iris Intelligent Imaging System device was evaluated for 1888 bitewing (955) and periapical (933) images. The dataset was split with roughly 30-70 images with and without image quality issues. Images were obtained from male and female patients, from a range of distinctly different geographic regions and age groups. Images were independently reviewed and annotated by three dentists. The results were compared to the consensus reference standard established by the three dentists.

The following key performance metrics were evaluated:

- Image-level standalone specificity
- Image-level standalone sensitivity
- Image level AUC (Area Under the ROC Curve)

The results met or exceeded all pre-specified performance goals. For instance, the observed image-level specificity was 99.0% with 95% CIs (98.2%, 99.6%) for Bitewing (BW) images and 98.1% with 95% CIs (96.9%, 99%) for Periapical (PA) images. The image-level sensitivity was 90.8% with 95% CIs (87.1%, 94.2%) for BW images and 93.9% with 95% CIs (91.3%, 96.1%) for PA images surpassing the required threshold for this endpoint. These results demonstrate that Overjet Iris Intelligent Imaging System performs safely and effectively within its intended use and is substantially equivalent to the identified predicate device.

12. Conclusion

The Overjet Iris Intelligent Imaging System is substantially equivalent to the predicate device VistaSoft 4.0 and VistaX 4.0. The differences do not raise any concerns about the safety or efficacy of the device.