December 5, 2025

Overjet, Inc.
% Alireza Sojoudi
VP of Machine Learning & Compliance
200 State St Ste 1220
BOSTON, MA 02109

Re: K251514
Trade/Device Name: Overjet CBCT Assist
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: November 6, 2025
Received: November 6, 2025

Dear Alireza Sojoudi:

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.

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 Radiologic 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251514

Device Name
Overjet CBCT Assist

Indications for Use *(Describe)*
Overjet CBCT Assist is a software for the analysis of dental and craniomaxillofacial Cone Beam Computed Tomography (CBCT) images. The software utilizes artificial intelligence/machine learning algorithms to provide automated segmentations, user-delineated or automated measurements, and 2D/3D visualizations. These tools are intended to assist dental professionals in their review and interpretation of CBCT images by facilitating anatomical assessment and supporting their diagnostic and treatment planning process. The device is not intended as a replacement for a complete clinician's review or their clinical judgement.

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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K251514 - 510(k) Summary

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

1. Date

December 3, 2025

2. Applicant

Overjet, Inc.
200 State St
Suite 1220
Boston, MA 02109
Contact Person: Dr. Alireza Sojoudi
Email: alireza.sojoudi@overjet.ai

3. Trade Name

Overjet CBCT Assist

4. Common Name

Automated Radiological Image Processing Software

5. Classification

Regulation: 21 CFR 892.2050
Classification Name: Medical Image Management and Processing System
Regulatory Class: Class II
Product code: QIH
Review Panel: Radiology

6. Device Description

Overjet CBCT Assist (OCBCTA) is a cloud-based software designed to assist dental professionals in the visualization and assessment of Cone Beam Computed Tomography (CBCT) images. The software enables interactive review of 3D CBCT data through volume rendering and multi-planar reconstruction (MPR) views and provides manual and automated tools to support diagnostic interpretation and treatment planning.

Overjet CBCT Assist uses machine learning-based segmentation algorithms to automatically identify and label anatomical and restorative structures, including permanent teeth, maxillofacial anatomy, and prior dental treatments such as implants, root canal therapy,

crowns, and fillings. These outputs support clinical workflows by enhancing visualization and enabling measurement of relevant features.

7. Indications for Use

Overjet CBCT Assist is a software for the analysis of dental and craniomaxillofacial Cone Beam Computed Tomography (CBCT) images. The software utilizes artificial intelligence/machine learning algorithms to provide automated segmentations, user-delineated or automated measurements, and 2D/3D visualizations. These tools are intended to assist dental professionals in their review and interpretation of CBCT images by facilitating anatomical assessment and supporting their diagnostic and treatment planning process. The device is not intended as a replacement for a complete clinician's review or their clinical judgement.

8. Predicate Device

a. Device: Relu Creator
Manufacturer: Relu BV
510(k): K233925
Product code: QIH
Common Name: Automated Radiological Image Processing System
Regulation: 21 CFR 892.2050
Classification Name: Medical image management and processing system

b. Device: Planmeca Romexis
Manufacturer: Planmeca Oy
510(k): K200572
Product Code: LLZ
Common Name: System, Image Processing, Radiological
Regulation: 21 CFR 892.2050
Classification Name: Medical Image Management and Processing System

9. Reference Device

Device: Overjet Charting Assist
Manufacturer: Overjet, Inc.
510(k): K241684
Product Code: QIH
Common Name: Automated Radiological Image Processing System
Regulation: 21 CFR 892.2050
Classification Name: Medical Image Management and Processing System

10. Indications for Use Comparison:

The indications for Use for Overjet CBCT Assist is determined to be substantially equivalent to the predicate devices - Relu Creator and Planmeca Romexis.

The subject and the predicate devices are intended to support the visualization, analysis, and interpretation of 3D CBCT data in dental and craniomaxillofacial applications. Each device assists qualified dental professionals in reviewing volumetric radiographic data to aid in the diagnostic process and treatment planning.

While the predicate devices include functionality to support design input for downstream dental solutions (e.g., surgical guides or treatment simulations), Overjet CBCT Assist is limited to diagnostic support. Despite this difference, the core intended use of supporting visualization, analysis and interpretation of 3D CBCT data remains consistent across all devices.

11. Technological Characteristics Comparison

Table 1: Comparison to Predicate Devices

Criteria	**Subject Device** **Overjet CBCT Assist** **Overjet, Inc.**	**Primary Predicate** **Relu Creator (K233925)** **Relu BV**	**Secondary Predicate** **Planmeca Romexis (K200572)** **Planmeca Oy**	**Comparison**
Classification Regulation	21 CFR 892.2050, Medical Image Management and Processing System	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 CBCT Assist is a software for the analysis of dental and craniomaxillofacial Cone Beam Computed Tomography (CBCT) images. The software utilizes artificial intelligence/machine learning algorithms to provide automated segmentations, user-delineated or automated measurements, and 2D/3D visualizations. These tools are intended to assist dental professionals in their review and interpretation of CBCT images by facilitating anatomical assessment and supporting their diagnostic and treatment planning process. The device is not intended as a replacement for a complete clinician's review or their clinical judgement.	Relu Creator is a software program for the management, transfer, and analysis of dental and craniomaxillofacial image information, and can be used to provide design input for dental solutions. It displays and enhances digital images from various sources to support the diagnostic process and treatment planning. It stores and provides these images within the system or across computer systems at different locations.	Planmeca Romexis is a medical imaging software intended for use in dental and medical care as a tool for displaying and visualizing dental and medical 2D and 3D image files from imaging devices, such as projection radiography and CBCT. It is intended for use by radiologists, clinicians, referring physicians and other qualified individuals to retrieve, process, render, diagnose, review, store, print, and distribute images of both adult and pediatric patients. Planmeca Romexis is also a preoperative software used for dental implant planning. Based on the planned implant position a model of a surgical guide for a guided implant surgery can be designed. The designed objects can be exported to manufacture a separate physical product.	All three devices are intended to support the visualization, analysis, and interpretation of 3D CBCT data in dental and craniomaxillofacial applications. While the predicate devices include downstream dental solutions, the subject device is limited to diagnostic support. These differences do not introduce new questions of safety or effectiveness.

Criteria	Subject Device Overjet CBCT Assist Overjet, Inc.	Primary Predicate Relu Creator (K233925) Relu BV	Secondary Predicate Planmeca Romexis (K200572) Planmeca Oy	Comparison
			Planmeca Romexis is also a preoperative software for simulating / evaluating surgical treatment options. Planmeca Romexis is also intended to be used for monitoring, recording, storing and displaying mandibular jaw positions and movements relative to the maxilla. Additionally, Planmeca Romexis includes monitoring features for Planmeca devices for maintenance purposes. The software is designed to work as a stand-alone or as an accessory to Planmeca imaging and Planmeca dental unit products in standard PC. The software is for use by authorized healthcare professionals. Use of the software for implant planning requires that the user has the necessary medical training in implantology and surgical dentistry. Use of the software for surgical treatment planning requires that the user has the necessary medical training in maxillofacial surgery. Indications of the dental implants do not change with guided surgery compared to conventional surgery.	
Platform & Requirements	Web-application	Web-application Local application	Standard PC hardware	The subject device is offered as a web application only.
Input File Types	Supports CBCT-based DICOM files: standard CBCT, enhanced CBCT, and craniofacial 3D DICOM formats.	Supports a broader range of image types used in dental workflows, including CBCT, IOS (intraoral scans), and FS (facial scans).	2D, 3D	The subject device is focused exclusively on 3D volumetric CBCT data while the predicate devices are capable of

Criteria	Subject Device Overjet CBCT Assist Overjet, Inc.	Primary Predicate Relu Creator (K233925) Relu BV	Secondary Predicate Planmeca Romexis (K200572) Planmeca Oy	Comparison
				ingesting a broader range of imaging modalities.
Output File Types	PDF	PDF report Common formats for dental and craniomaxillofacial treatment planning applications (STL, DICOM, PLY, OBJ)	PDF report	All three devices provide output as PDF reports. The predicate Relu Creator also supports export in standard 3D planning formats as compared to the subject device.
Functions and Capabilities	• Multi-Planar Reconstruction Views • 3D Volume Rendering • Virtual Panoramic view reconstruction • Image enhancement and manipulation (Brightness, Contrast) • AI-based segmentation of dental and craniomaxillofacial anatomy, as well as past restorations. • Measurement - Distance (length, diameter, perimeter), Area, Angle, Signal intensity • Implant Site Evaluation • 3rd molar surgery planning by generating linear measurement to nearby critical structures • Supports airway evaluation by reporting minimum cross-sectional area	• Multi-Planar Reconstruction Views • 3D Volume Rendering • Virtual Panoramic view reconstruction • Image enhancement and manipulation (Brightness, Contrast) • AI-based segmentation of dental and craniomaxillofacial anatomy, as well as past restorations. • Preoperative Planning • STL export supported for general anatomical structures.	• Multi-Planar Reconstruction Views • 3D Volume Rendering • Virtual Panoramic view reconstruction • Image enhancement and manipulation (Brightness, Contrast) • Segmentation of the jaws • Linear, angular, area and volumetric measurements • Implant Planning • Preoperative software for simulating / evaluating surgical treatment • Airway volume measurement	The differences in specific features do not introduce new questions of safety or effectiveness.

Table 2: Comparison to Reference Device

Criteria	Subject Device Overjet CBCT Assist Overjet, Inc.	Reference Device Overjet Charting Assist (K241684) Overjet Inc.
Classification Regulation	21 CFR 892.2050, Medical Image Management and Processing System	21 CFR 892.2050, Medical Image Management and Processing System

Intended Use/Indications for Use	Overjet CBCT Assist is a software for the analysis of dental and craniomaxillofacial Cone Beam Computed Tomography (CBCT) images. The software utilizes artificial intelligence/machine learning algorithms to provide automated segmentations, user-delineated or automated measurements, and 2D/3D visualizations. These tools are intended to assist dental professionals in their review and interpretation of CBCT images by facilitating anatomical assessment and supporting their diagnostic and treatment planning process. The device is not intended as a replacement for a complete clinician's review or their clinical judgement.	Overjet Charting Assist is a Medical Image Management and Processing System (MIMPS) intended to detect natural dental structures including detection of tooth anatomy (enamel, pulp), and tooth numbering, as well as dental structures added through past restorative treatments: implants, crowns, endodontic treatment (previous root canal treatment), fillings. The device is intended to assist dental professionals in producing dental charts based on image analysis. The Overjet Charting Assist detects these findings on bitewing (BW) and periapical (PA) images for patients with primary and/or permanent teeth (Ages 5 and above), and panoramic (Pano) radiographs for patients with only permanent teeth. The device is not intended as a replacement for a complete clinician's review or clinical judgment that considers other relevant information from the image or patient history.
Input Data	3D CBCT volumes (DICOM format)	2D dental radiographs
Technology	AI-based algorithms for the detection of dental and craniomaxillofacial anatomy, as well as past restorations.	AI-based algorithms for the detection of natural dental structures and structures added through past restorative treatment.

11.1 Comparison to Predicate device:

The technological characteristics of the subject device are nearly identical to those of the predicate devices, with only minor differences. All three devices support the visualization and analysis of 3D DICOM-compliant CBCT data and are designed to aid dental professionals in diagnostic evaluation and treatment planning. Overjet CBCT Assist incorporates AI-based segmentation to identify anatomical and restorative structures within CBCT volumes, consistent with capabilities described in the predicate devices. Manual measurement tools such as linear, angular, and area assessments are available to support clinical workflows, similar to those available in the identified predicates.

While Overjet CBCT Assist is focused exclusively on 3D CBCT data, the predicate devices additionally support other imaging modalities (e.g., intraoral scans, facial scans, 2D radiographs) and include optional features for treatment design or simulation. These differences reflect typical variability in feature sets among medical imaging software and do not introduce new questions of safety or effectiveness.

11.2 Comparison to Reference Device:

The Overjet Charting Assist (K241684) is included as a reference device to support the scientific testing methods used for the subject device. Both the subject device and the reference device are modules within the same Overjet Platform and utilize AI-based segmentation, classification, and visualization frameworks. The only difference between the two devices is the input image modality (2D radiograph vs 3D CBCT data).

12. Performance Testing

Overjet conducted comprehensive nonclinical performance testing to support a determination of substantial equivalence for Overjet CBCT Assist. This included software verification and validation (V&V) testing in accordance with FDA guidance “General Principles of Software Validation” (FDA, January 2002) and the FDA-recognized consensus standard IEC 62304:2006+A1:2015 for software lifecycle processes. 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.

Additionally, Overjet performed a standalone clinical performance study using retrospective CBCT data to evaluate the accuracy of automated segmentations and measurements. The study included comparison to ground truth annotations generated by licensed oral and maxillofacial radiologists.

A total of 100 CBCT scans were included in the pivotal study. These scans were obtained from a demographically and anatomically diverse patient population and were acquired using devices from multiple CBCT scanner manufacturers. Images were independently reviewed and annotated by three U.S.-licensed oral and maxillofacial radiologists and dentists. The resulting segmentations served as the reference standard against which the device’s outputs were compared.

The following key performance metrics were evaluated:

- Instance-level sensitivity for dental anatomy, restorative structures, and maxillofacial anatomy
- Instance-level specificity for restorative structures
- Dice similarity coefficient for all segmented structures
- Measurement accuracy (Mean Absolute Error (MAE) and Root Mean Square Error (RMSE)) for automated linear measurements displayed in MPR views
- Tooth-level sensitivity and accuracy for tooth numbering

No adverse effects or complications were identified in the retrospective evaluation, as the software functions as an image processing and visualization aid and does not directly interact with patients.

The results met or exceeded all pre-specified performance goals. For instance, the observed instance-level sensitivity for restorative structures was 87.0% with 95% CI (82.3%, 91.2%) and the instance-level sensitivity for dental anatomy was 93.9% with 95% CI (91.7%, 95.9%) surpassing the required threshold for this endpoint. Dice scores for segmented structures passed their individually associated thresholds across all evaluated classes. Measurement accuracy for linear distances also met the target thresholds for MAE and RMSE. These results demonstrate that Overjet CBCT Assist performs safely and effectively within its intended use and is substantially equivalent to the identified predicate devices.

13. Conclusion

Overjet CBCT Assist is substantially equivalent to the predicate device, Relu Creator and Planmeca Romexis. The differences do not raise any concerns about the safety or efficacy of the device.