September 9, 2024

Overjet Inc
% Deepthi Paknikar
Associate Director - Clinical & Regulatory Affairs
50 Milk Street, 16th Floor
BOSTON, MA 02109

Re: K241681
Trade/Device Name: Overjet Image Enhancement Assist
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: June 11, 2024
Received: August 14, 2024

Dear Deepthi Paknikar:

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
Diagnostoc 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.

Submission Number *(if known)*

K241681

Device Name

Overjet Image Enhancement Assist

Indications for Use *(Describe)*

Overjet Image Enhancement Assist is an image processing software that can be used for image enhancement in dental radiographs viewed in the Overjet device platform. It is an optional tool to be used for image quality enhancement.

The software improves image quality by:
- Reducing Noise: Utilizing a learning-based algorithm for noise reduction in bitewing and periapical images.
- Enhancing Contrast and Sharpness: Applying standard, non-learning based techniques to enhance contrast and sharpness for bitewing, periapical, and panoramic images.

Raw images will be acquired and reviewed using the dental clinics standard imaging acquisition and viewing software. This device is part of the Overjet platform alone, it is not intended to replace their own diagnostic imaging system.

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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K241681 - 510 (k) Summary

Applicant Name: Overjet, Inc
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Applicant Contact: Dr. Deepthi Paknikar
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Correspondent Name: Overjet, Inc
Correspondent Address: 50 Milk Street 16th Floor Boston MA 02109 United States
Correspondent Contact Telephone: 630-201-1612
Correspondent Contact: Dr. Deepthi Paknikar
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Date Prepared: August 15th, 2024

Device Trade Name: Overjet Image Enhancement Assist
Common Name: Automated Radiological Image Processing System
Classification Name: Medical image management and processing system
Regulation Number: 892.2050
Product Code: QIH

Legally Marketed Predicate Device: SubtleMR (2.3.x)
Common Name: Automated Radiological Image Processing System
Classification Name: Medical image management and processing system
Regulation Number: 892.2050
Predicate Product Code: LLZ
Predicate K number: K223623

Device Description Summary

Overjet Image Enhancement is a Software as a Medical Device (SaMD) that enhances dental radiographic images within the Overjet Platform, intended for use by dental providers in clinics or hospitals. It supports routine dental images, including bitewing, periapical, and panoramic images, viewed within the Overjet Platform.

The software enhances image quality by reducing noise with a learning-based algorithm for bitewing and periapical images, and by improving contrast and sharpness using standard, non-learning based techniques. For panoramic images, standard enhancement techniques improve contrast and sharpness without learning-based noise reduction. The enhancement feature can be toggled on and off by the user within the Overjet Platform. AI predictions for findings such as caries, calculus, etc. are run as specified for each FDA cleared device and are run on unenhanced (original) images only. There is no modification to the output of other FDA cleared Overjet devices when the image enhancement feature is applied.

Intended Use/Indications for Use

Overjet Image Enhancement Assist is an image processing software that can be used for image enhancement in dental radiographs viewed in the Overjet device platform. It is an optional tool to be used for image quality enhancement.

The software improves image quality by:

- Reducing Noise: Utilizing a learning-based algorithm for noise reduction in bitewing and periapical images.

- Enhancing Contrast and Sharpness: Applying standard, non-learning based techniques to enhance contrast and sharpness for bitewing, periapical, and panoramic images.

Raw images will be acquired and reviewed using the dental clinics standard imaging acquisition and viewing software. This device is part of the Overjet platform alone, it is not intended to replace their own diagnostic imaging system.

Indications for Use Comparison

The subject device is substantially equivalent to the predicate device, with minor differences. Both devices operate within standard imaging workflows, enhancing images for viewing. The subject device uses one model for denoising with standard techniques for sharpness and contrast, while the predicate uses two learning based models. Both devices utilize the PyTorch framework and similar loss functions, and these differences do not raise new questions of safety and effectiveness.

Technological Comparison

The technological characteristics of the subject device are nearly identical to those of the predicate device, with only minor differences. The subject device operates within the standard dental imaging workflow, allowing users to acquire, review, and store images as usual, with the enhanced images available for optional viewing on the Overjet Platform via a web browser. Unlike the predicate device, which uses two models for sharpness enhancement and denoising, the subject device employs a single model for denoising and standard techniques for sharpness and contrast. Both devices utilize the PyTorch machine learning framework and employ similar loss functions, including L1 and SSIM. These differences do not present new questions of safety and effectiveness, ensuring the subject device's substantial equivalence to the predicate.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Overjet conducted the following performance testing: software verification and validation testing, a study that utilized retrospective data to demonstrate that the software enhanced image quality (quantification report and expert clinical evaluation).

The test methods were highly similar to those of the predicate device. The study on retrospective images was divided into two tests: 1) a quantification report to provide results on contrast-to-noise ratio (CNR) and peak-signal-to-noise ratio (PSNR), and 2) a Likert expert clinical evaluation. All tests passed successfully.

The results of this testing demonstrated that the performance of the Overjet Image Enhancement Assist device is substantially equivalent to that of the predicate device.