



February 23, 2024

Overjet, Inc
% Deepthi Paknikar
Senior Manager, Clinical & Regulatory Affairs
50 Milk Street
16th Floor
BOSTON, MA 02109

Re: K233590

Trade/Device Name: Overjet Charting Assist
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: January 23, 2024
Received: January 23, 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.

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,

A stylized signature of "Lu Jiang" in a cursive script, overlaid on a large, light blue "FDA" watermark.

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

Indications for Use

510(k) Number (if known)
K233590

Device Name
Overjet Charting Assist

Indications for Use (Describe)

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.

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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510 (k) Summary

K233590

Applicant Name: Overjet, Inc

Applicant Address: 50 Milk Street 16th Floor Boston MA 02109 United States

Applicant Contact Telephone: 630-201-1612

Applicant Contact: Dr. Deepthi Paknikar

Applicant Contact Email: deepthi.paknikar@overjet.ai

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

Correspondent Contact Email: deepthi.paknikar@overjet.ai

Device Trade Name: Overjet Charting Assist

Common Name: Medical image management and processing system

Classification Name: Medical image management and processing system

Regulation Number: 892.2050

Product Code: QIH

Legally Marketed Predicate Device: Denti.AI Auto-Chart

Predicate Product Code: LLZ

Predicate K number: K222054

Device Description Summary

Overjet Charting Assist is a Medical Image Management and Processing System (MIMPS) device aimed to assist dental professionals in detecting dental structures and producing dental charting data based on interpretation of 2D dental radiographs. The device is 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.

Intended Use/Indications for Use

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.

Indications for Use Comparison

Both the subject Overjet Charting Assist and predicate Denti.AI Auto-Chart devices are intended for use to assist dental professionals (users), in detecting dental structures and producing dental charting based on the interpretation of intraoral and extraoral 2D radiographs (bitewing, periapical, and panoramic). Both devices assist in detecting natural dental structures (teeth), and dental structures added through past restorative treatment (implants, crowns, endodontic treatment, fillings). The subject and predicate device differ in that the subject device detects teeth including the whole tooth/tooth numbering and enamel, pulp. An additional difference is that the predicate device is indicated for patients ≥ 22 , whereas the subject device is indicated for patients with primary and/or permanent dentition for bitewing and periapical images for patients age 5 and above and patients with permanent dentition for panoramic images. The minor changes in indications does not change the intended use of the device.

The predefined Acceptance Criteria established for the standalone study are based on the current state of dental practice and are appropriate to demonstrate that the Overjet Charting Assist device performs in accordance with specifications and will meet user needs and intended uses. Based on the detailed comparison between the predicate devices and the subject devices, the software verification testing and performance testing, the Overjet charting Assist device can be found substantially equivalent to the predicate device.

Technological Comparison

The primary predicate device provides automatic charting based on AI based image analysis, whereas the Overjet device outputs semi-automatic segmented dental structures (dental tooth anatomy, structures from past restorative treatment, and tooth numbering) on 2D radiographs with corresponding list of findings next to the image to be used to assist users in creating dental charts. The Overjet device provides users autonomy to show/hide, delete, and adjust the highlighted dental structures as needed. Both devices utilize AI based image analysis. Both devices support 2-D intraoral or extra oral dental radiographs. Both devices are cloud based platforms. The minor difference in technological characteristics do not raise a concern of substantial equivalence as demonstrated by the performance testing of the Overjet device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Standalone performance of the Overjet Charting Assist device was evaluated for 634 images. Images were obtained from male and female patients with primary and permanent dentition, from various clinics across the U.S.. The results were compared to a robust consensus reference standard established by trained dentists via majority pixel voting.

Primary endpoints included tooth level sensitivity of past restorative treatment, dental tooth anatomy, and tooth level sensitivity (overall classification accuracy) of tooth numbering. There was one unique image per subject in the dataset. Clinical sites were from across the U.S. and collected from 44 distinct clinics. The image type distribution of the dataset was: 259 Bitewing Images, 239 Periapical Images, and 136 Panoramic Images. There were 337 images from female subjects and 297 images from male subjects.

The following results were obtained as a result of the standalone study, and the results demonstrate that the device performs well when compared to a robust reference standard.

Gender: Tooth level sensitivity of past restorative structures by Gender was 89.5% for Females and 86.9% for Males, specificity was 98.3% for Females and 97.9% for Males. Tooth level Sensitivity of dental tooth anatomy was 95.6% for Females and 96.2% for Males.

Geography: The Tooth level sensitivity estimates vary across the 44 different clinical sites across the US, from all U.S. regions (Southeast, Southwest, Midwest, Northeast, West). The tooth level sensitivity for dental tooth anatomy estimates range from 86.8% to 100%. Tooth level sensitivity for past restorative structures by clinical site ranged from 71.6% to 100%, specificity ranged from 91.5%-100%.

Age: The Tooth level standalone sensitivity was analyzed on patients aged 5-60+ with primary and permanent teeth on bw/pa images, patients with only permanent teeth on pano images as part of the standalone study. The sensitivity ranged from 83.6%-90.5% across various age groups for past restorative structures, specificity ranged from 95.1% to 98.8%. The sensitivity ranged from 89.2%-98.4% for dental tooth anatomy. The Distribution of Age Range in the dataset is as follows:

Age Group, n(%)	Images/Subjects* N=634
5-11	89
12-18	131
19-30	94
31-45	123
46-60	89
60+	108

Tooth Level Standalone Analysis for subgroups of past restorative structures, by restoration type with 95% CI's are as follows:

Fillings: Sensitivity of 0.799 (0.770, 0.824), Specificity of 0.986 (0.983, 0.990)

RCT: Sensitivity of 0.943 (0.918, 0.966), Specificity of 0.999 (0.998, 1.000)

Crown: Sensitivity of 0.954 (0.937, 0.970), Specificity of 0.994 (0.992, 0.996)

Implant: Sensitivity of 0.898 (0.860, 0.935), Specificity of 0.998 (0.997, 0.999)

Tooth Level Standalone Analysis for subgroups of dental tooth anatomy, by anatomy type with 95% CI's are as follows:

Enamel: Sensitivity of 0.949 (0.943, 0.956), Specificity of 0.863 (0.831, 0.893)

Pulp: Sensitivity of 0.856 (0.840, 0.872), Specificity of 0.951 (0.938, 0.961)

Tooth Numbering Classification Accuracy by Subgroups of Radiograph Type and Tooth Type with 95% CI's are as follows:

Panoramic Image: 0.992 (0.988, 0.996)

Bitewing Image: 0.989 (0.983, 0.995)

Periapical Image: 0.969 (0.954, 0.983)

Primary Teeth: 0.988 (0.970, 1.000)

Permanent Teeth: 0.988 (0.984, 0.991)

Tooth level standalone sensitivity for past restorative structures was 88.3% with 95% CI's of (86.6%, 90.1%).

Tooth Level standalone sensitivity for dental tooth anatomy (enamel/pulp) was 95.9% with 95% CI's of (95.1%, 96.5%).

Tooth Level standalone sensitivity (Overall Classification Accuracy) for dental tooth numbering was 98.8% with 95% CI's of (98.4%, 99.1%).

Dice for Dental Tooth Anatomy resulted in a Mean Std. Dev. 0.836 (0.098) with 95% CI's (0.832, 0.842).

Dice for Past Restorative Structures resulted in a Mean Std. Dev. 0.918 (0.078) with 95% CI's (0.914, 0.923).

The Mean % Reduction per image in Manual Charting Operations with (95% CI) when using the OChA device is 80.5% (79.0%, 81.9%).

PPV for dental tooth anatomy at the tooth level was 0.967 with 95% CI's of (0.960, 0.973)

NPV for dental tooth anatomy at the tooth level was 0.710 with 95% CI's of (0.672, 0.745)

PPV for past restorative structures at the tooth level was 0.958 with 95% CI's of (0.948, 0.967)

NPV for past restorative structures at the tooth level was 0.945 with 95% CI's of (0.935, 0.954)

Analysis was conducted across these sensor manufacturers: sirona, vatech, acteon, carestream, dexis, e2v, gendex, hamamatsu, kavo, and shick.

All conducted tests produced results that exceeded predefined acceptance criteria. The Summary Performance "Manual charting reduction rate" metric shows that the number of manual operations is reduced by over 80% when using findings produced by Overjet Charting Assist for compared to the fully manual entry of the same dental charting information.

Manual operations without the Overjet Charting Assist (OChA) involve loading restorative and anatomy information from radiographs into a chart, with each finding requiring a specific number of manual operations. On the other hand, with OChA, teeth, crowns, root canals, implants, and fillings are detected, reducing manual operations. However, false positive predictions may increase manual operations due to the need for correction. The percentage reduction in manual operations with OChA compared to without is calculated using the following formula: Percentage reduction is calculated using the following formula :

$100 * (\text{manual operations without OChA} - \text{Manual operations with OChA}) / (\text{Manual Operations without OChA})$

In addition, thorough verification and validation testing were conducted and documented to support the adequate performance of the Overjet Charting Assist device and its integration to the Overjet platform.

Conclusion

Both the predicate device and the Overjet Charting Assist device share the same intended purpose. Despite minor technological differences, these differences in technological features do not raise concerns regarding safety or effectiveness. The verification and validation testing and predefined Acceptance Criteria set for the standalone study are aligned with current dental practices and are deemed suitable for demonstrating that the Overjet Charting Assist functions according to specifications, meeting user needs and intended uses.

Following the information reviewed as part of this 510k, it can be concluded that the Overjet Charting Assist is substantially equivalent to the predicate device.