



December 5, 2023

Adra Corporation
% Moeini Golnaz
Regulatory Consultant
GM Consulting
1425 Golden Meadow Square
SAN JOSE, CA 95117

Re: K232440

Trade/Device Name: Adravisio Perio
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: November 9, 2023
Received: November 9, 2023

Dear Moeini Golnaz:

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 font, overlaid on a large, light blue "FDA" logo.

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)

K232440

Device Name

Adravision Perio

Indications for Use (Describe)

Adravision Perio is a radiological semi-automated image processing software device intended to aid dental professionals in the measurements of mesial and distal bone levels associated with each tooth from bitewing and periapical radiographs. It should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis. The intended users of Adravision Perio are trained professionals including, but not limited to, dentists and dental hygienists.

The intended patient population of the device is patients living in the United States, who are 22 years old or older, and that do not have any remaining primary teeth. Adra Corporation has not evaluated the performance of the device on primary dentition.

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 (K232440)

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

Date: Dec 1, 2023

Applicant: MedEdge Consulting
Golnaz Moeini
golnaz.moeini@gmail.com
408-504-3187

Trade Name: AdraVision Perio

Common Name: Dental Image Processing Software

Regulation Name: Medical Image Management and Processing System

Regulation Number: 21 CFR 892.2050

Product Code: Device QIH

Classification: Device Class II

Description: AdraVision Perio is a Software as a Medical Device (SaMD) intended to aid dentists in the measurement of mesial and distal bone levels associated with each tooth on bitewing and periapical dental radiographs of permanent teeth in patients 22 years of age or older.

The device provides assistance to dentists by suggesting the measurement of interproximal bone levels. The device recommendations are for reference only and the user should review associated radiographs, view annotations and modify annotations if needed. The device is not intended as a replacement for a complete clinician's review or their clinical judgment because users can take into account other relevant information from the image, intraoral exam or patient history.



Indications for Use:

AdraVision Perio is a radiological semi-automated image processing software device intended to aid dental professionals in the measurements of mesial and distal bone levels associated with each tooth from bitewing and periapical radiographs. It should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis.

The intended users of AdraVision Perio are trained professionals including, but not limited to, dentists and dental hygienists.

The intended patient population of the device is patients living in the United States, who are 22 years old or older, and that do not have any remaining primary teeth. Adra Corporation has not evaluated the performance of the device on primary dentition.

Predicate Device:

Overjet Inc., Overjet Dental Assist, 510(k): K210187
 Trade Name: Overjet Dental Assisst
 Classification Name: Medical Image Management and Processing System
 Regulation number: 21 CFR 892.2050, Product Code: LLZ, Class II

Substantial Equivalence:

Feature/ Function	Proposed Device AdraVision Perio Device	Primary Predicate Overjet Dental Assist K210187	Identical?
Data source	Bitewing and periapical radiographs	Bitewing and periapical radiographs	Yes
Image input sources ¹	Images imported from the radiographic device, or from the practice management system, or manually uploaded into the system	Images imported from the radiographic device, or from the practice management system	No
Image format ²	DICOM, JPEG, JPG, PNG, TIFF, TIF, JFIF or BMP file	jpg, png, jfif, eop, etp, jif	No
Platform ³	Web- Edge, Chrome, Firefox, Brave, Safari	Web - Edge, Chrome, Firefox	No
End user	Dentist, dental hygienist	Dentist, dental hygienist	Yes
Patient population	The intended patient population of the device is	The intended patient population of the device is	Yes

Feature/ Function	Proposed Device AdraVision Perio Device	Primary Predicate Overjet Dental Assist K210187	Identical?
	patients living in the United States, who are 22 years old or older, that do not have any remaining primary teeth.	patients living in the United States, who are 22 years old or older, and that do not have any remaining primary teeth.	
Operating system	Any	Any	Yes
User Interface	Mouse, keyboard, trackpad	Mouse, keyboard, trackpad	Yes
Patient Database Compatibility	SQL	SQL	Yes
Image Viewing	Full, thumbnail	Full, thumbnail	Yes
Features detected	Bone level	Bone level	Yes
Model output	Line segments	Line segments	Yes

Discussion of Differences

Both the proposed and the predicate device are designed to be similar in intended use, indications for use, intended users, and intended use environment. Both devices utilize machine learning technologies to measure interproximal bone levels in dental radiographs and allow users to visualize the radiographs with annotations, add their own annotations and use the information as part of their diagnostic decision.

Other similarities include both software have no direct contact with the patient and both systems utilize standard image types.

A few technological differences between the proposed and the predicate device are discussed below. These differences are deemed to not raise questions of safety and efficacy are detailed below.

Image input sources¹ - Both the proposed device and predicate support image input sources from the radiographic device and the practice management system. The proposed device



additionally accepts manual upload of radiographs into the software which the predicate device does not support. The V&V testing for the device demonstrates the device's capability in supporting the analysis of all image input sources. This minor difference does not raise new questions of safety and efficacy compared to the predicate device.

Image formats² - Both the proposed device and predicate support image formats of JPG, PNG, and JFIF. The proposed device additionally accepts DICOM, JPEG, TIFF, TIF and BMP image formats that the predicate device does not support. The V&V testing for the device demonstrates the device's capability in supporting the analysis of all the designated image formats and demonstrates that this minor difference does not raise new questions of safety and efficacy compared to the predicate device.

Platform³ - Both the proposed device and predicate device support common browsers of Edge, Chrome and Firefox. The proposed device additionally works on Safari and Brave. The V&V testing for the device demonstrates the device's capability to function on designated browsers and demonstrates that this minor difference does not raise new questions of safety and efficacy compared to the predicate device.

Performance Testing:

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The software for this device was considered as a Basic Documentation Level, since a failure or latent flaw could indirectly result in minor injury to the patient or user through incorrect or delayed information through the action of a care provider.

Bench Testing

Adra completed standalone studies according to the predefined protocols to demonstrate the safety and effectiveness of the AdraVision Perio device for its indications for use.

Bench testing included evaluation of performance based upon a ground truth data set utilizing (i) Object Key Similarity (OKS) Assessment, and (ii) Length Measurement Assessment.

In the OKS Assessment, AdraVision Perio was evaluated with a total dataset of 340 dental radiographs (bitewing and periapical radiographs) and evaluated the precision and recall against the key points labeled by a ground truther within those radiographs.

Metric	Bitewing	Periapical
Precision	91.0%	84.8%
Recall	94.0%	89.3%

In the Length Measurement Assessment, AdraVision Perio was evaluated with a dataset of 78 dental radiographs and evaluated the sensitivity and specificity against the consensus CAL length measurements labeled by three (3) ground truthers within those radiographs.

Metric	Bitewing	Periapical
Sensitivity	90.7 %	92.5 %
Specificity	94.3 %	86.8 %
Mean Absolute Error	0.434 mm	0.504 mm

Analysis of study results for patient age, gender, clinic site, region of the mouth and sensor type were performed as subgroup analysis.

AdraVision Perio also obtained an overall tooth number classification accuracy of 91.8% in the OKS study and 93.2% in the Length Assessment demonstrating that it can well locate the CAL measurements on the relevant tooth number and tooth surface.

Our bench testing showed that AdraVision Perio software met the prespecified performance requirements when evaluated against ground truth labeling and demonstrated robustness and reliability in drawing CAL line segments in clinically relevant locations with accurate length on the relevant tooth.

No adverse effects or complications were recorded associated with this bench study since all radiographs were collected retrospectively and no treatment decisions were made.

Conclusion:

AdraVision Perio is substantially equivalent to the predicate device, Overjet Dental Assist. Differences do not raise any concerns about the safety or efficacy of the device.