May 30, 2025

Audax d.o.o.
℅ Josh Ellis
Consultant
Trellis Enterprises LLC
PO Box 1406
BOULDER, UT 84716

Re: K243005
Trade/Device Name: AudaxCeph Cephalogram Analysis Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: April 29, 2025
Received: April 30, 2025

Dear Josh Ellis:

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 Radiological 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)*
K243005

Device Name
AudaxCeph Cephalogram Analysis Software

Indications for Use *(Describe)*
AudaxCeph Cephalogram Analysis Software is designed for use by specialized dental practices for storing and presenting patient images and assisting in treatment planning. Results produced by the software's treatment planning tools are dependent on the interpretation of trained and licensed practitioners.

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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K243005 510(k) Summary

SUBMITTER INFORMATION:

DATE PREPARED: September 23, 2024 (Revised 05/30/2025)

510(k) SUBMITTER: Audax d.o.o.
Tehnološki park 18c, 1000
Ljubljana, Slovenia
Phone: 00386 1 200 4050
510(k) CONTACT: Josh Ellis

DEVICE INFORMATION:

DEVICE TRADE NAME: AudaxCeph Cephalogram Analysis Software
COMMON NAME: Dental imaging software
CLASSIFICATION NAME: Medical Image Management and Processing System
REGULATION NUMBER: 21 CFR §892.2050
PRODUCT CODE: QIH
DEVICE CLASS: II

PREDICATE DEVICE:

The predicate device chosen for this submission is CephX Cephalometric Analysis Software (K231396) cleared on January 31, 2024, legally marketed by Orca Dental AI, Ltd.

No reference devices were used in this submission.

To identify a suitable predicate, the short list of devices in Product Codes LLZ & QIH that have similar Indications for Use (cephalogram analysis) were analyzed according to applicable FDA Guidance.[1]

DEVICE DESCRIPTION:

AudaxCeph Cephalogram Analysis Software is a software-only device intended for use by specialty dental professionals in the development of 2D dental treatment planning utilizing cephalogram landmarks. Cephalogram imagery must be captured separately and inputted to the program using a variety of common file formats (BMP, JPG, JPEG, PNG, TIFF). Landmarks are digitized, structures are traced, measurements can be taken, and various custom analysis types are possible. The software assists in orthodontic treatment planning by providing image analysis, superimpositions, and VTO (visualized treatment objective).

The software is offered in two different client configurations: A desktop client as an application locally-hosted on a PC (“AudaxCeph Ultimate” and “Essentials”), and a cloud-hosted solution (“AudaxCeph WeDoCeph”) which is accessible by a web browser client. Both are intended for use only by specialty dental professionals, have no patient-

[1] “Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission” (2023). Retrieved from: https://www.fda.gov/media/171838/download

interacting components or interfaces, and all analysis capabilities of the AudaxCeph Cephalogram Analysis software that inform clinical decisions are within the capabilities of the CephX Cephalometric Analysis Software predicate device.

INDICATIONS FOR USE:
AudaxCeph Cephalogram Analysis Software is designed for use by specialized dental practices for storing and presenting patient images and assisting in treatment planning. Results produced by the software's treatment planning tools are dependent on the interpretation of trained and licensed practitioners.

The Indications for Use statement for the AudaxCeph device is not identical to the predicate device; however, the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. There are no differences in the use environment, intended users, or anatomical structures of use between the devices. Both the subject device and predicate device have the same intended use of storing and presenting patient images and assisting in dental treatment planning.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE
Cephalogram analysis involves landmark placement and various measurements between landmarks to aid in dental treatment planning. The technological principle for both the subject AudaxCeph Cephalogram Analysis Software and predicate CephX Cephalometric Analysis Software (K231396) is to utilize computer software to digitize landmark placement and measurement tasks. A comparison between the technological and use characteristics of the subject and the predicate device, summarized in Table 1, demonstrates that the design, technology, and Indications for Use of the AudaxCeph Cephalogram Analysis Software are substantially equivalent to the predicate device.

Table 1: Comparison of Subject Device with Predicate Device

Feature	SUBJECT: AudaxCeph Cephalogram Analysis Software	PREDICATE: CephX Cephalometric Analysis Software
510(k) Number		K231396
Intended Use	Designed for use by specialized dental practices for storing and presenting patient images and assisting in treatment planning. Results produced by the software's treatment planning tools are dependent on the interpretation of trained and licensed practitioners.	Indicated for use by dentists who provide orthodontic treatment for image analysis, simulation, profilogram, VTO (Visual Treatment Objective), and patient consultation. Results produced by the software's diagnostic, treatment planning and simulation tools are dependent on the interpretation of trained and licensed practitioners or dentists. The device is only for use on patients 14 years old and above.
Product Code	QIH	QIH
Type of Use (Rx /OTC)	Rx	Rx
User	Orthodontic, oral maxillofacial surgery, and dental-specialty practices.	Orthodontic, oral maxillofacial surgery, and dental-specialty practices.
Platform	IBM-compatible PC or PC network	IBM-compatible PC or PC network
Processor	x64-based processor or higher	x64-based processor or higher
Software Access	Local PC hosted or cloud hosted	Cloud-hosted
Materials, Additives, & Finishing Agents	N/A, software-only device	N/A, software-only device
Energy Delivery	N/A, software-only device	N/A, software-only device
Anatomical Area	Dental, Maxilla, Mandible	Dental, Maxilla, Mandible
Device Features		
2D Image Acquisition/Digitizing (radiological/image capture interface/controls)	No	No
2D Automatic Tracing w/Clinician Review	Yes	Yes
2D Image Measurements	Yes	Yes
2D Image Superimposition	Yes	Yes
2D Growth Forecast	Yes	Yes
2D Treatment Simulation	Yes	Yes
2D Custom Analysis Editor	Yes	Yes
2D Orthognathic Surgical Planning	No	No
Implant Module	No	No
3D Image Capability	No	No
Landmarks	60	21

The subject device and the predicate device have the following technological differences:

1. The wording of the Indications for Use are slightly different but both have the same Intended Use. The predicate includes a restriction limiting device usage to patients 14 years of age or above while the subject device does not include such a restriction. The removal of an age limitation from the Indications for Use in the subject device is consistent with other similar software on the market and consistent with a practitioner's ability to do manual tracing on a patient of any age. The appropriateness and validity of the various named analyses to mixed-dentition populations is well-documented in the literature and generally known and understood in the population of intended users.
2. The subject device is capable of operating in PC-based standalone software configuration instead of only a cloud-hosted configuration like the predicate device.
3. The predicate device is capable of identifying 21 landmarks while the subject device is capable of identifying 60.

All analysis capabilities of the AudaxCeph Cephalogram Analysis software that inform clinical decisions are within the capabilities of the CephX Cephalometric Analysis Software predicate device.

NON-CLINICAL PERFORMANCE TESTING

Non-clinical testing, including software verification tests, evaluated:

- Unit testing
- Performance Testing
- Manual Testing
- Integration Testing
- System and Regression Testing

The device has been designed, manufactured, and tested in accordance with the FDA Voluntary Consensus Standards and Guidance outlined in Table 2. Software verification and validation activities have been successfully performed on the software package, including assurance that functions work as designed, measurements are accurate, performance requirements and specifications have been met, and that all hazard mitigations have been fully implemented. All testing has met the predetermined acceptance values.

Table 2: Non-Clinical Testing Standards & Guidance

Standard	Title	FDA Recognition #
IEC 62304 ed. 1.1	Medical device software - Software life cycle processes	13-79
IEC 62366-1 ed 1.1	Medical devices - Part 1: Application of usability engineering to medical devices	5-129
ISO 14971:2019	Medical devices - Application of risk management to medical devices	5-125

Standard	Title	FDA Recognition #
IEC TR 80002-1 ed. 1.0	Medical device software - Part 1: Guidance on the application of ISO 14971 to medical device software	13-34
FDA Guidance (09-27-2023)	Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions	Docket: FDA-2021-D-1158
AAMI TIR57:2016	Principles for medical device security - Risk management.	13-83

To verify the accuracy of automatically placed landmarks, first an acceptance criteria study was performed to assess the accuracy of manual landmark placement. The results of that study, combined with a literature review of other studies, was used to establish the acceptance criteria upon which automatic landmark detection accuracy was evaluated. The accuracy study involved automatically-detected landmarks reviewed by orthodontists. The results of the accuracy study, as shown in Table 3, indicate that the device met all acceptance criteria for automatic landmark detection.

Table 3: Automatic Landmark Detection Accuracy Study Results

Parameter		Acceptance Criteria	Conclusion
MRE (mm)	Lateral	≤ 1.5	PASS
	Frontal (PA)	≤ 2.5	PASS

CLINICAL PERFORMANCE TESTING

No clinical testing was required to support substantial equivalence.

SUBSTANTIAL EQUIVALENCE CONCLUSION:

The intended use and fundamental technological capabilities of cephalometric tracing/landmark analysis, image superimposition, and treatment planning of the AudaxCeph Cephalogram Analysis Software and that of the predicate device are identical. Although the predicate device is a cloud-based software and AudaxCeph also offers a desktop-based interface, the difference does not raise any new questions regarding safety or effectiveness. Both devices have been verified and validated using internal protocols according to FDA-recognized consensus standards. The information presented in this submission sufficiently demonstrates that the proposed device is as safe and effective as the predicate device.

Thus, the AudaxCeph Cephalogram Analysis Software is substantially equivalent for all regulatory purposes to the legally marketed predicate device CephX Cephalometric Analysis Software (K231396).