March 5, 2026

Orca Dental AI Ltd.
% Moshe Melamed
RA Manager
Dolev St 4
RA'ANANA, 4366204
ISRAEL

Re: K252538
Trade/Device Name: CEPHX3D
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: January 28, 2026
Received: January 28, 2026

Dear Moshe Melamed:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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)*
K252538

Device Name
CEPHX3D

Indications for Use *(Describe)*
CephX3D is a software program for the analysis of dental and craniomaxillofacial image information and can be used to provide design input for dental solutions. It processes and displays digital images from various sources to support the diagnostic process and treatment planning. It is intended for use in patients aged 12 and older.

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) PREMARKET NOTIFICATION

Type of submission: Traditional 510(k)

510(k) Summary

K252538

CEPHX3D

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1. **Submitter Name and Address:**

Orca Dental AI Ltd.

Ha-Tidhar St 5, Ra'anana

Zip Code 4366507, Israel

2. **Contact details**

a. Primary contact person details:
Name: Daniel Abraham

Title: CEO

Email: danny@orca-dental.ai

Phone Number: +972 52 333 3776

Office: +972 52 333 3776

b. Secondary contact person details:
Name: Moshe Melamed

Title: RA Manager

Email: moshe@cephx.com

Phone Number: +972 53878997

3. **Device details:**

Device Trade Name (proprietary name):

CEPHX3D

Device Common Name:

Medical image management and processing system

Product Classification:

- **Name:** Medical image management and processing system
- **Product code:** QIH
- **Regulation No:** 892.2050
- **Documentation Level:** Basic
- **Panel:** Radiology

4. **Predicate Device(s):**

We claim substantial equivalence to the Relu Creator (K233925). Both devices share an identical intended use and a similar technological basis, allowing CephX3D to maintain an equivalent safety and effectiveness profile.

5. Device Software Description

CEPHX3D is a cloud-based software-as-a-service (SaaS) solution designed for the automated processing and visualization of dental and maxillofacial Cone Beam Computed Tomography (CBCT) data. The software utilizes deep learning algorithms to perform three-dimensional segmentation of key anatomical structures, including skeletal bone (mandible and maxilla), the full dentition, and the inferior alveolar nerve (IAN).

5.1. Technological Principle

The device utilizes deep learning algorithms, specifically 3D U-Net Convolutional Neural Networks (CNNs) optimized for volumetric medical imaging, to segment specific anatomical structures from DICOM datasets. The software backend is built on the Spring Framework (Java) and hosted on Apache Tomcat (AWS Cloud), ensuring robust processing and data security.

5.2. Key Functionalities & Workflow

1. **Ingestion:** The software receives standard DICOM files from CBCT scanners.
2. **Automated Segmentation:** The AI engine processes the volume to automatically segment and reconstruct:
   - **Bony Structures:** Mandible and Maxilla.
   - **Dentition:** Individual teeth (Crowns and Roots).
   - **Vital Structures:** The Inferior Alveolar Nerve (IAN) pathway.
3. **Visualization & Refinement:** The resulting 3D models (STL format) are displayed in an interactive web-based 3D Viewer (WebGL). This viewer provides tools for rotation, zooming, transparency adjustment, and manual refinement of segmentation boundaries.
4. **Data Utilization:** The finalized 3D models are utilized for treatment planning, or exported to third-party CAD/CAM software for appliance design.

5.3. Visualization & Analysis

The resulting 3D models (STL format) are displayed in an interactive web-based 3D Viewer (WebGL). This viewer provides tools for:

- **Manipulation:** Rotation, zooming, and transparency adjustment.
- **Measurement:** Linear (mm), angular (degrees), and volumetric (mm^3) analysis.

- **Refinement:** Manual tools for clinicians to adjust segmentation boundaries if necessary.

6. Indications for use & Intended use:

CephX3D is a software program for the analysis of dental and craniomaxillofacial image information and can be used to provide design input for dental solutions. It processes and displays digital images from various sources to support the diagnostic process and treatment planning. It is intended for use in patients aged 12 and older.

Clinical Purpose: The primary clinical purpose of CEPHX3D is to provide dental professionals with high-fidelity, three-dimensional anatomical reconstructions to enhance the precision of orthodontic and surgical treatment planning. By automating the identification and segmentation of critical structures—including the mandible, maxilla, full dentition, and the inferior alveolar nerve (IAN)—the software allows for the immediate visualization of complex spatial relationships that are difficult to discern on traditional 2D radiographs. This enables clinicians to perform more accurate cephalometric analyses, simulate potential tooth movements, and identify high-risk surgical pathways (such as the proximity of roots to the nerve canal) with greater objective confidence, ultimately supporting safer and more predictable clinical outcomes.

Intended users:

CephX3D is intended for use by licensed dentists, orthodontists, and other dental specialists who work with CBCT images, including but not limited to endodontists, prosthodontists, oral surgeons, and maxillofacial radiologists. Users should have a working knowledge of CBCT image interpretation, dental anatomy, and cephalometric analysis. Before using the software, the user will be trained on its proper and safe use. Training includes reading the User manual and viewing of an instructional video.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

This section compares the technological characteristics of CEPHX3D with the predicate device, Relu Creator (K233925), to support the substantial equivalence determination

under 21 CFR 807.92(a)(6). The comparison evaluates design, components, inputs, outputs, and operational features, focusing on similarities and differences in functionality. Table 1 provides a side-by-side analysis of key technological parameters. Where differences exist, they are assessed to ensure they do not raise new questions of safety or effectiveness, with justifications provided in **Section 8 (Justification for intended use comparison)**.

Table 1: Comparison of Technological Characteristics with Predicate Device

Parameter	**CEPHX3D**	**Relu Creator (K233925)**	**Comparison**
Platform	Web application	Web application	Same
User Interface	Graphical user interface	Graphical user interface	Same
Component	Web application	Web application	Same
Input Data Types	CBCT images	CBCT, intraoral scans (IOS), facial scans (FS)	Similar – Both use CBCT as the primary input. CEPHX3D's exclusive use of CBCT aligns with its validated scope and does not affect safety or effectiveness. See Section 8.
Output Data Formats	STL, DICOM	STL, DICOM, PLY, OBJ	Similar – Both share STL and DICOM, sufficient for treatment planning. Relu Creator's additional PLY and OBJ formats are optional and do not impact safety or effectiveness. See Section 8.
Image Measurement Tools	Distance measurements	Distance measurements	Same
Image Viewing	3D viewing and editing	3D viewing and editing	Same
Image Manipulation	Brightness/contrast adjustment	Brightness/ contrast adjustment	Same

Parameter	**CEPHX3D**	**Relu Creator (K233925)**	**Comparison**
Image Annotation	Available	Available	Same
Treatment Planning & Simulation	3D simulation	3D simulation	Same
Supported Anatomical Area	Dental, maxilla, mandible, airway	Dental, maxilla, mandible, airway	Same
Key Differences in Technological Characteristics			
Data Storage & Transfer	Relies on Parent System (AWS)	Integrated Storage	Different, See Section 8.
Image Processing Focus	Processes and displays digital images (AI-driven)	Displays and enhances digital images	CEPHX3D emphasizes AI processing; Relu Creator prioritizes enhancement. Both achieve comparable 3D modeling outcomes. See Section 8.

The Indications for Use statements for CEPHX3D and Relu Creator are compared below to highlight similarities and differences in wording and scope, supporting the technological comparison and SE assessment:

- **CEPHX3D Indications for Use:**

  "CephX3D is a software program for the analysis of dental and craniomaxillofacial image information and can be used to provide design input for dental solutions. It processes and displays digital images from various sources to support the diagnostic process and treatment planning. It is intended for use in patients aged 12 and older."

- **Relu Creator (K233925) Indications for Use:**

  "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."

8. Justification for intended use comparison

The intended use of CEPHX3D—to analyze dental and craniomaxillofacial imaging data to support diagnostic processes and provide design input for dental treatment planning—is identical to that of Relu Creator, as established in Section 6 (Indications for use & Intended use). Both devices aim to assist dental professionals in treatment planning through image analysis, with overlapping clinical purposes despite minor differences in scope.

- **Management functionality:** The "management and transfer" functions in Relu Creator's indications represent supplementary capabilities rather than a distinct intended use. CEPHX3D, as part of the broader CephX platform (cleared under CEPHX- Cephalometric Analysis Software K231396), inherits these functions from its parent application, which manages and transfers imaging data via Amazon Web Services (AWS). CEPHX3D focuses specifically on 3D analysis and output generation, streamlining its Indications for Use to reflect this specialization. This narrowing does not change the overarching purpose—supporting dental treatment planning. No new safety or effectiveness questions arise, as the parent CephX platform's clearance validates these ancillary functions.
- **Processing vs. Enhancing Wording:** A subtle difference exists where CEPHX3D "processes and displays digital images" while Relu Creator "displays and enhances digital images." Despite the distinct terminology, these phrases describe functionally equivalent actions in the context of their intended use. CEPHX3D's "processing" emphasizes its AI-driven generation of 3D models and measurements from CBCT images, while Relu Creator's "enhancing" suggests improving visual quality for interpretation. In practice, both devices perform the same essential function: transforming imaging data into usable outputs (e.g., 3D models) to support treatment planning.

- **Patient Population Difference:** CEPHX3D specifies use in patients aged 12 and older, unlike Relu Creator, which has no age restriction. This limitation reflects the population tested in CEPHX3D's performance evaluation, targeting adolescents and adults commonly undergoing orthodontic or craniomaxillofacial procedures. The restriction aligns with clinical practice and does not alter the intended use.

9. Performance Data

Software verification and validation testing were conducted to verify that CEPHX3D meets its performance specifications and intended use requirements. The validation strategy comprised two complementary studies:

Quantitative Non-Clinical Performance Testing: Non-clinical performance was established through a quantitative analytical validation of 30 CBCT datasets against an expert-refined "Ground Truth" established via the Refined Automated Segmentation (R-AS) methodology.

The algorithm demonstrated exceptional anatomical fidelity across all categories, exceeding all pre-defined success criteria:

- **Skeletal Bone:** Achieved a mean Dice Similarity Coefficient (DSC) of 0.9827 and a mean Root Mean Square (RMS) surface error of 0.0623 mm.
- **Dentition:** Achieved a mean DSC of 0.9993 and a mean RMS of 0.0136 mm.
- **Inferior Alveolar Nerve (IAN):** Achieved a mean DSC of 0.9861 and a mean RMS of 0.1668 mm. Most notably, the nerve segmentation achieved a mean 95th percentile Hausdorff Distance (HD95) of 0.00 mm, indicating zero clinically significant boundary outliers.

Ground Truth Validation (Secondary Objective): The reliability of the reference standard was validated through an Inter-Rater Reliability (IRR) study. The two independent experts achieved an Overall Global Mean DSC of 0.9905, confirming that the R-AS methodology provides a stable, reproducible, and objective anatomical baseline. Per the study

protocol, no formal adjudication was required as all expert-to-expert spatial discrepancies remained significantly below the 0.5 mm escalation trigger.

Qualitative Clinical Performance Testing: Clinical validation involved a retrospective review of 53 CBCT cases by a panel of independent, board-certified specialists. The study met its primary endpoint with 100% (53/53) of cases rated as "Clinically Acceptable." Inter-rater reliability analysis confirmed the robustness of these results, showing Fleiss' Kappa scores of 1.0 (Perfect Agreement) for bone and nerve models, and 0.80 (Strong Agreement) for dentition.

10. Conclusion

The combined non-clinical and clinical performance data demonstrate that CEPHX3D is as safe, as effective, and performs as well as the predicate device. Based on the comparison of intended use, technological characteristics, and the validation results summarized above, CEPHX3D is determined to be substantially equivalent to Relu Creator (K233925).