January 31, 2024

Orca Dental AI LTD
℅ Daniel Abraham
CEO
10 Hamanofim Street
HERZLIYA, PO 4672561
ISRAEL

Re: K231396
Trade/Device Name: CEPHX- Cephalometric Analysis Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: January 4, 2024
Received: January 5, 2024

Dear Daniel Abraham:

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,

Lu Jiang

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231396

Device Name
CEPHX – Cephalometric Analysis Software

Indications for Use *(Describe)*
CEPHX - Cephalometric Analysis Software is 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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1. SUBMITTER NAME AND ADDRESS:

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2. CONTACT DETAILS

a. Primary contact person details:

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b. Secondary contact person details:

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3. DEVICE DETAILS:

Device Trade Name (proprietary name):

CEPHX – Cephalometric Analysis Software

Device Common Name:

Medical Imaging Software

Product Classification:

- **Name:** Medical image management and processing system
- **Product code:** QIH

- **Regulation No:** 892.2050
- **Class:** II
- **Panel:** Radiology

4. PREDICATE DEVICE(S):

Device Trade Name (proprietary name):

WebCeph

Clearence No.:

K220903

Device Common Name:

Medical Imaging Software

Product Classification:

- **Name:** Medical image management and processing system
- **Product code:** LLZ
- **Regulation No:** 892.2050
- **Class:** II

Panel: Radiology

5. DEVICE DESCRIPTION

CEPHX – Cephalometric Analysis Software uses cephalometric x-ray images to help dentists study the relationships between bone and soft tissue landmarks and can be used to diagnose facial abnormalities throughout an orthodontic treatment.

As a first step, the user uploads a 2D cephalometric image and the software generates 99 cephalometric landmark points. The landmarks are important points in a lateral radiographic view of the teeth, jaws and base of the skull, and are used in multiple cephalometric analyses, which have proven to be a useful aid in basic orthodontic differential diagnosis. Once the landmark points are created, the user can generate a full

report by choosing from a large selection of built-in analysis methods or create a customed analysis using the Analysis Wizard. The report can be printed or downloaded according to the user selection.

6. INDICATIONS FOR USE & INTENDED USE:

CEPHX - Cephalometric Analysis Software is 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 and above.

Patient population:

Patients 14 years old and above.

Intended users:

The software is to be used by qualified dentists.

Before any use of the software, the user has to be trained on proper and safe use of the software.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Parameter	CEPHX	WebCeph K220903	Comparison
Indication for Use	CEPHX - Cephalometric Analysis Software is a software indicated for use by dentists who provide orthodontic treatment for image analysis, simulation, profilogram, VTO (Visual Treatment Objective)	WebCeph is a software indicated for use by dentists who provide orthodontic treatment for image analysis, simulation, profilogram, VTO/STO (Visual Treatment	Different - Has no safety or security impact on the product. The STO and age

Parameter	CEPHX	WebCeph K220903	Comparison
	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.	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 the use of patients above 7 years old.	differences are detailed below.
Platform	IBM-compatible PC or PC network	IBM-compatible PC or PC network	Same
Operating System	Microsoft Window 7, 8, 10	Microsoft Window 7, 8, 10	Same
User Interface	Mouse, Keyboard	Mouse, Keyboard	Same
CPU processor type	x64-based processor or higher	x64-based processor or higher	Same
Image Communication Standard	BMP, JPG, PNG	BMP, JPG, PNG	Same
Modality Support	X-ray or CT	X-ray or CT	Same
Component	Client (Internet Browser)	Client (Internet Browser)	Same
Database Compatibility	MySQL	PostgreSQL	Different - Has no safety, security or performance impact on the product. The difference is explained and detailed below.
Image Measurement tools	Linear distance, angle	Linear distance, angle	Same
Image viewing	Full, side by side, thumbnail, Zoom in / out, template.	Full, side by side, thumbnail, Zoom in / out, template.	Same
Image manipulation	Brightness, contrast, flip, rotate, annotation, cephalometric tracing.	Brightness, contrast, flip, rotate, annotation, cephalometric tracing.	Same

Parameter	CEPHX	WebCeph K220903	Comparison
Cephalometric tracing	In addition to the user-configured analysis, standard orthodontic tracing analysis include: Downs, Steiner, Jarabek, McNamara, Ricketts, Eastman, Kim, Wits.	In addition to the user-configured analysis, standard orthodontic tracing analysis include: Downs, Steiner, Jarabek, McNamara, Ricketts, Eastman, Kim, Wits.	Same
Implant module	None	None	Same
3D imaging capability	None	None	Same
Image annotation	Paint, draw, magnify, line drawing, distance measure (px or mm), 3-point angle, ruler(calibrate), select region crop.	Paint, draw, magnify, line drawing, distance measure (px or mm), 3-point angle, ruler(calibrate), select region crop.	Same
Treatment Planning, Simulation and follow up	-Translate, tip and rotate incisors, reposition molars, rotate mandible and skeletal structures - Superimpose one or more growth tracings over original tracing.	-Translate, tip and rotate incisors, reposition molars, rotate mandible - Superimpose one or more growth tracings over original tracing.	Different - Has no safety or security impact on the product. The Skeletal structure difference is explained and detailed below.
Supported Area	Dental, Maxilla, Mandible	Dental, Maxilla, Mandible	Same

8. INDICATION FOR USE COMPARISON:

The subject device doesn't have the STO (Surgical Treatment Objective) - this is a feature to outline soft tissues. Note having this feature doesn't impact the product safety, security or performance. In addition, the phrase "the use of" was changed to "use on" to make it clearer that it is referring to the target patient population. Lastly, the predicate device is intended for use in patients aged 7 and up, while the subject device is intended for use in patients aged 14 and up. This difference does not raise any new questions of safety and effectiveness since we are just excluding the age group we do not have clinical data at this time.

9. TECHNOLOGICAL CHARACTERISTICS

CEPHX - Cephalometric Analysis Software is a software that does not contact the patient, nor does it control any life sustaining devices. Results produced by the software's diagnostic, treatment planning tools are dependent on the interpretation of trained and licensed practitioners or dentists.

The software is a supporting tool, providing recommendation for tracing landmarks on Ceph images, but not replacing the action performed by the clinician.

The technological characteristics are as described in the table above.

10. PERFORMANCE DATA

A study for Verification of Artificial-Intelligence (AI) computer generated landmarks in cephalometric tracing versus manual landmarks provided by orthodontic specialists was conducted. In general, The study aimed to verify the accuracy of AI-generated landmarks in cephalometric tracing compared to manually generated landmarks by orthodontic specialists. CephX, the AI-based cephalometric analysis software, was evaluated for its reliability and precision in detecting critical cephalometric landmarks compared to three experienced orthodontic specialists. The study design involved the comparison of 21 clinically significant landmarks detected automatically by the AI algorithm to the manually detected landmarks by the three orthodontic specialists, with a margin of up to 2.0mm considered "pass" and a margin above this range considered "fail".

The results showed that 99% of landmarks were identified, meeting the study endpoint and pre-defined hypothesis. The secondary endpoints also showed very good accuracy without any outliers. The device's stand-alone performance was established against the ground truth, and the acceptance criteria of at least 85% of cases meeting the "pass" criteria were satisfied.

11. CONCLUSIONS

The CEPHX - Cephalometric Analysis Software and the predicate device have similar intended use, indication for use, technological features and performance characteristics.

Performance and software validation data demonstrate that the differences between the CEPHX - Cephalometric Analysis Software and the predicate do not raise any new questions of safety and effectiveness.