

**K231396 CEPHX- Cephalometric Analysis Software**Jan 31, 2024  
261 days to decisionK231396 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k231396/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 15, 2023
Decision date	Jan 31, 2024
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orca Dental AI , Ltd.</b>
Location	Ra&apos;Anana, IL
Contact	Daniel Abraham
510(k) history	2 submissions · 2 cleared · 2024-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231396/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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