

K252538 CEPHX3DMar 5, 2026
205 days to decisionK252538 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k252538/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Aug 12, 2025
Decision date	Mar 5, 2026
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Orca Dental AI , Ltd.
Location	Ra'Anana, IL
Contact	Moshe Melamed
510(k) history	2 submissions · 2 cleared · 2024-2026

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