

## K253930 Overjet Iris Intelligent Imaging System

Apr 10, 2026  
122 days to decisionK253930 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k253930/>

### SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Dec 9, 2025
Decision date	Apr 10, 2026
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

### APPLICANT

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Company	<b>Overjet, Inc.</b>
Location	Boston, MA, US
Contact	Gayatri Sekaran
Website	<a href="https://www.overjet.com">https://www.overjet.com</a>
510(k) history	11 submissions · 11 cleared · 2021-2026

Overjet, Inc. is a dental AI software company based in Boston, US. The company develops artificial intelligence platforms for dental imaging, clinical diagnosis, and administrative automation. Overjet serves dentists, dental service organizations, insurers, and dental educators with FDA-cleared AI solutions. Overjet has received FDA 510(k) clearances from total submissions since its first clearance in 2021. The company specializes exclusively in Radiology devices, with all submissions focused on AI-assisted imaging analysis and clinical decision support. The latest cleara...

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Device record: <https://www.510kdatabase.net/k253930/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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