

**K212519 Overjet Caries Assist**May 10, 2022  
273 days to decisionK212519 · Product code: **MYN** · Radiology  
Source: <https://www.510kdatabase.net/k212519/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Medical Image (MYN)
Date received	Aug 10, 2021
Decision date	May 10, 2022
Days to decision	273 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	Wardah Inam
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...