

K233738 Overjet Caries Assist-PediatricMar 4, 2024
103 days to decisionK233738 · Product code: **MYN** · Radiology
Source: <https://www.510kdatabase.net/k233738/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Medical Image (MYN)
Date received	Nov 22, 2023
Decision date	Mar 4, 2024
Days to decision	103 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Overjet, Inc.
Location	Boston, MA, US
Contact	Deepthi Paknikar
Website	https://www.overjet.com
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/k233738/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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