

K222746 Overjet Caries AssistMar 27, 2023
196 days to decisionK222746 · Product code: **MYN** · Radiology
Source: <https://www.510kdatabase.net/k222746/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Medical Image (MYN)
Date received	Sep 12, 2022
Decision date	Mar 27, 2023
Days to decision	196 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Overjet, Inc.
Location	Boston, MA, US
Contact	Adam Odeh
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...
