

**K231678 Overjet Periapical Radiolucency Assist**Sep 21, 2023  
104 days to decisionK231678 · Product code: **MYN** · Radiology  
Source: <https://www.510kdatabase.net/k231678/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Medical Image (MYN)
Date received	Jun 9, 2023
Decision date	Sep 21, 2023
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Overjet, Inc.</b>
Location	Boston, MA, US
Contact	Deepthi Paknikar
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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