

K241681 Overjet Image Enhancement AssistSep 9, 2024
90 days to decisionK241681 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k241681/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Automated Radiological Image Processing Software (QIH) |
| Date received | Jun 11, 2024 |
| Decision date | Sep 9, 2024 |
| Days to decision | 90 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...