

K250753 VELMENI for DENTISTS (V4D)Sep 2, 2025
174 days to decisionK250753 · Product code: **MYN** · Radiology
Source: <https://www.510kdatabase.net/k250753/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Medical Image (MYN)
Date received	Mar 12, 2025
Decision date	Sep 2, 2025
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	Velmeni, Inc.
Location	Sunnyvale, CA, US
Contact	Ishveen Anand
510(k) history	2 submissions · 2 cleared · 2024-2025

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