

**K242437 Smile Dx®**May 14, 2025  
271 days to decisionK242437 · Product code: **MYN** · Radiology  
Source: <https://www.510kdatabase.net/k242437/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Medical Image (MYN)
Date received	Aug 16, 2024
Decision date	May 14, 2025
Days to decision	271 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cube Click, Inc.</b>
Location	New York, NY, US
Contact	Richard Ricci
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Innolitics</b>
Contact	Meritxell Martinez

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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