

K253009 DS Core DetectJan 7, 2026
110 days to decisionK253009 · Product code: **MYN** · Radiology
Source: <https://www.510kdatabase.net/k253009/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Medical Image (MYN)
Date received	Sep 19, 2025
Decision date	Jan 7, 2026
Days to decision	110 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dentsply Sirona, Inc.
Location	York, PA, US
Contact	Deepthi Paknikar
Website	http://www.dentsply.com
510(k) history	21 submissions · 21 cleared · 2019-2026

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