

K253565 SureSmile SoftwareMar 4, 2026
107 days to decisionK253565 · Product code: **PNN** · Dental
Source: <https://www.510kdatabase.net/k253565/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthodontic Software (PNN)
Date received	Nov 17, 2025
Decision date	Mar 4, 2026
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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