

K212770 VisionDec 21, 2021
112 days to decisionK212770 · Product code: **PNN** · Dental
Source: <https://www.510kdatabase.net/k212770/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthodontic Software (PNN)
Date received	Aug 31, 2021
Decision date	Dec 21, 2021
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Softsmile, Inc.
Location	Lewes, DE, US
Contact	Khamzat Asabaev
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Hyman, Phelps, & Mcnamara
Contact	Allyson B. Mullen

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

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