

K212828 BRIUS Planner SoftwareOct 1, 2021
28 days to decisionK212828 · Product code: **PNN** · Dental
Source: <https://www.510kdatabase.net/k212828/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthodontic Software (PNN)
Date received	Sep 3, 2021
Decision date	Oct 1, 2021
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Brius Technologies, Inc.
Location	Carrollton, TX, US
Contact	Mehdi Roein-Peiker
510(k) history	2 submissions · 2 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Prime Path Medtech
Contact	Breanne Butler

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

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