

K192701 DIBS (Digital Indirect Bonding System)Apr 21, 2020
207 days to decisionK192701 · Product code: **PNN** · Dental
Source: <https://www.510kdatabase.net/k192701/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthodontic Software (PNN)
Date received	Sep 27, 2019
Decision date	Apr 21, 2020
Days to decision	207 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Orthoselect, LLC
Location	American Fork, UT, US
Contact	Steven N. Gardner
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Emma International Consulting Group, Inc.
Contact	Carmine Jabri

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192701/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026