

**K180941 Ortho System**Oct 17, 2018  
203 days to decisionK180941 · Product code: **PNN** · Dental  
Source: <https://www.510kdatabase.net/k180941/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthodontic Software (PNN)
Date received	Mar 28, 2018
Decision date	Oct 17, 2018
Days to decision	203 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>3Shape A/S</b>
Location	Copenhagen, DK
Contact	Kristian Worziger Nielsen
510(k) history	8 submissions · 8 cleared · 2016-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180941/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026