

**K152086 3Shape Ortho System**Apr 28, 2016  
276 days to decisionK152086 · Product code: **PNN** · Dental  
Source: <https://www.510kdatabase.net/k152086/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthodontic Software (PNN)
Date received	Jul 27, 2015
Decision date	Apr 28, 2016
Days to decision	276 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>3Shape A/S</b>
Location	Copenhagen, DK
Contact	Hanne 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/k152086/> 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 3, 2026