

K163677 Ortho SystemApr 20, 2017
114 days to decisionK163677 · Product code: **PNN** · Dental
Source: <https://www.510kdatabase.net/k163677/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthodontic Software (PNN)
Date received	Dec 27, 2016
Decision date	Apr 20, 2017
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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