

K191911 3Shape Splint DesignNov 27, 2019
133 days to decisionK191911 · Product code: **PNN** · Dental
Source: <https://www.510kdatabase.net/k191911/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthodontic Software (PNN)
Date received	Jul 17, 2019
Decision date	Nov 27, 2019
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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