

K161884 Ortho SystemApr 19, 2017
282 days to decisionK161884 · Product code: **MQC** · Dental
Source: <https://www.510kdatabase.net/k161884/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Jul 11, 2016
Decision date	Apr 19, 2017
Days to decision	282 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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