

K191836 Ceramill A-SplintDec 20, 2019
164 days to decisionK191836 · Product code: **MQC** · Dental
Source: <https://www.510kdatabase.net/k191836/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Jul 9, 2019
Decision date	Dec 20, 2019
Days to decision	164 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Amann Girrback AG
Location	Koblach, AT
Contact	Debora Engel
510(k) history	3 submissions · 3 cleared · 2017-2019

REGULATORY CONSULTANT

Consulting firm	Emergo Europe Consulting
Contact	Rachel Paul

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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