

K211415 GR Splint Resin SystemOct 21, 2021
168 days to decisionK211415 · Product code: **MQC** · Dental
Source: <https://www.510kdatabase.net/k211415/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	May 6, 2021
Decision date	Oct 21, 2021
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pro3dure Medical GmbH
Location	Iserlohn, DE
Contact	Frank Gischer
510(k) history	4 submissions · 4 cleared · 2020-2022

REGULATORY CONSULTANT

Consulting firm	Regulatory and Quality Solutions, LLC
Contact	Patricia Kontoudis

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

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