FDA 510(k) Premarket Notification

K211415 GR Splint Resin System

CLEARED

Oct 21, 2021
168 days to decision

K211415 · 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