FDA 510(k) Premarket Notification

K231775 GR Resin System MSI

CLEARED

Aug 8, 2024
419 days to decision

K231775 · Product code: **MQC** · Dental
Source: https://www.510kdatabase.net/k231775/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Jun 16, 2023
Decision date	Aug 8, 2024
Days to decision	419 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pro3Dure Medical**
Location	Iserlohn, DE
Contact	Frank Gischer
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Kontoudis Regulatory Consulting, LLC**
Contact	Patricia Kontoudis

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