

K231793 RODIN 3D Resin SPLINT, Hard/FlexMar 26, 2024
280 days to decisionK231793 · Product code: **MQC** · Dental
Source: <https://www.510kdatabase.net/k231793/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Jun 20, 2023
Decision date	Mar 26, 2024
Days to decision	280 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Belport Company, Inc., Gingi-Pak
Location	Camarillo, CA, US
Contact	Jingtian Peng
510(k) history	11 submissions · 11 cleared · 2020-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231793/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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