

K223798 Glidewell TuffSplint™ Appliance ResinFeb 17, 2023
60 days to decisionK223798 · Product code: **MQC** · Dental
Source: <https://www.510kdatabase.net/k223798/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Dec 19, 2022
Decision date	Feb 17, 2023
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Prismatik Dentalcraft, Inc.
Location	Newport Beach, CA, US
Contact	Jiahe Li
510(k) history	57 submissions · 57 cleared · 2010-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223798/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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