

K253798 UltraPrint-Dental Hard Splint UVMar 2, 2026
94 days to decisionK253798 · Product code: **MQC** · Dental
Source: <https://www.510kdatabase.net/k253798/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Nov 28, 2025
Decision date	Mar 2, 2026
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guangzhou Heygears IMC., Inc.
Location	Guangzhou, CN
Contact	Meifang Liu
510(k) history	3 submissions · 3 cleared · 2022-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253798/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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