

K232087 Dental LT Comfort ResinFeb 16, 2024
218 days to decisionK232087 · Product code: **MQC** · Dental
Source: <https://www.510kdatabase.net/k232087/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mouthguard, Prescription (MQC)
Date received	Jul 13, 2023
Decision date	Feb 16, 2024
Days to decision	218 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Formlabs Ohio, Inc.
Location	Millbury, OH, US
Contact	Ritika Sharma
510(k) history	3 submissions · 3 cleared · 2022-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232087/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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