

K210940 LuxaPrint Ortho PlusSep 3, 2021
158 days to decisionK210940 · Product code: **MQC** · Dental
Source: <https://www.510kdatabase.net/k210940/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Mar 29, 2021
Decision date	Sep 3, 2021
Days to decision	158 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dmg Digital Enterprises SE
Location	Hamburg, DE
Contact	Stephan Schafer
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Delphi Medical Device Consulting, Inc.
Contact	Pamela Papineau

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210940/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026