

K200125 Thermoforming Sheet MaterialsOct 28, 2020
281 days to decisionK200125 · Product code: **MQC** · Dental
Source: <https://www.510kdatabase.net/k200125/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Jan 21, 2020
Decision date	Oct 28, 2020
Days to decision	281 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Erkodent Erich Kopp GmbH
Location	Pfalzgrafenweiler, DE
Contact	Hans-Peter Kopp
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Ajw Technology Consultants, Inc.
Contact	Jon Ward

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

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