

K212017 Thermeo SystemApr 8, 2022
284 days to decisionK212017 · Product code: **MQC** · Dental
Source: <https://www.510kdatabase.net/k212017/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Jun 28, 2021
Decision date	Apr 8, 2022
Days to decision	284 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pro3dure Medical GmbH
Location	Iserlohn, DE
Contact	Frank Gischer
510(k) history	4 submissions · 4 cleared · 2020-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212017/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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