

K241311 Thermoforming Sheet Materials (Track A)Aug 2, 2024
85 days to decisionK241311 · Product code: **MQC** · Dental
Source: <https://www.510kdatabase.net/k241311/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	May 9, 2024
Decision date	Aug 2, 2024
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Thermoforming Sheet Materials (Track B); Thermoforming Sheet Materials (Track E); Thermoforming Sheet Materials (Track Bleach)

APPLICANT

Company	Bernhard F?rster GmbH
Location	Pforzheim, DE
Contact	Stefan F?rster
510(k) history	1 submissions · 1 cleared · 2024-2024

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