

K220257 PermadyneFeb 1, 2022
1 days to decisionK220257 · Product code: **ELW** · Dental
Source: <https://www.510kdatabase.net/k220257/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Jan 31, 2022
Decision date	Feb 1, 2022
Days to decision	1 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	3M Deutschland GmbH
Location	Bavaria D-82228 Seefeld, DE
Contact	Ruediger Franke
510(k) history	12 submissions · 12 cleared · 2012-2022

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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

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