

K213201 DeltaFil, DeltaFil ConditionerJun 1, 2022
245 days to decisionK213201 · Product code: **EMA** · Dental
Source: <https://www.510kdatabase.net/k213201/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Sep 29, 2021
Decision date	Jun 1, 2022
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dmg Chemisch Pharmazeutische Fabrik GmbH
Location	Germany, GR
Contact	Stephan Schaefer
510(k) history	4 submissions · 4 cleared · 1994-2022

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)

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