

K222357 DenMat Glutaraldehyde DesensitizerAug 9, 2022
5 days to decisionK222357 · Product code: **KLE** · Dental
Source: <https://www.510kdatabase.net/k222357/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Aug 4, 2022
Decision date	Aug 9, 2022
Days to decision	5 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Denmat Holding, LLC
Location	Lompoc, CA, US
Contact	Murisa Woodlin
510(k) history	2 submissions · 2 cleared · 2022-2025

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222357/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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