

K240714 Insure® UniversalJul 24, 2024
131 days to decisionK240714 · Product code: **EMA** · Dental
Source: <https://www.510kdatabase.net/k240714/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Mar 15, 2024
Decision date	Jul 24, 2024
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement
Other names	Insure® Universal Automix

APPLICANT

Company	Cosmedent, Inc.
Location	Chicago, IL, US
Contact	Gary Chuven
510(k) history	28 submissions · 28 cleared · 1986-2024

REGULATORY CONSULTANT

Consulting firm	Deltamed GmbH
Contact	Michael Zimmermann

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

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