

K214118 Riva Cem AutomixAug 30, 2022
243 days to decisionK214118 · Product code: **EMA** · DentalSource: <https://www.510kdatabase.net/k214118/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Dec 30, 2021
Decision date	Aug 30, 2022
Days to decision	243 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sdi Limited
Location	Bayswater, AU
Contact	Antonella Kotefski
510(k) history	6 submissions · 6 cleared · 2010-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k214118/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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