

K162960 TotalC-RamMar 14, 2017
141 days to decisionK162960 · Product code: **EMA** · Dental
Source: <https://www.510kdatabase.net/k162960/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Cement, Dental (EMA)
Date received	Oct 24, 2016
Decision date	Mar 14, 2017
Days to decision	141 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Itena Clinical
Location	Laval, CA
Contact	Charles Peyre
510(k) history	8 submissions · 8 cleared · 2013-2017

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