

K160345 Glass Ionomer CementMar 3, 2017
389 days to decisionK160345 · Product code: **EMA** · Dental
Source: <https://www.510kdatabase.net/k160345/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Feb 8, 2016
Decision date	Mar 3, 2017
Days to decision	389 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shandong Huge Dental Material Corporation
Location	Rizhao City, CN
Contact	Steven Song
510(k) history	8 submissions · 8 cleared · 2016-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160345/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026