

K152652 PackFil Dual Cured Resin Modified Glass Ionomer Restorative CementApr 5, 2016
202 days to decisionK152652 · Product code: **EMA** · Dental
Source: <https://www.510kdatabase.net/k152652/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Sep 16, 2015
Decision date	Apr 5, 2016
Days to decision	202 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gaia Dental Products, Inc.
Location	Meriden, CT, US
Contact	WEITAO JIA
510(k) history	1 submissions · 1 cleared · 2016-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152652/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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