

K163568 SHOFU RESIN GLAZEAug 16, 2017
240 days to decisionK163568 · Product code: **EBD** · Dental
Source: <https://www.510kdatabase.net/k163568/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coating, Filling Material, Resin (EBD)
Date received	Dec 19, 2016
Decision date	Aug 16, 2017
Days to decision	240 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Shofu Dental Corporation
Location	San Marcos, CA, US
Contact	Mauro Malzyner
510(k) history	38 submissions · 38 cleared · 2011-2025

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