

K162261 CERAMAGE UPJan 11, 2017
153 days to decisionK162261 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k162261/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Aug 11, 2016
Decision date	Jan 11, 2017
Days to decision	153 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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