

K172106 SHOFU MZ Primer PlusAug 31, 2017
50 days to decisionK172106 · Product code: **KLE** · DentalSource: <https://www.510kdatabase.net/k172106/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Jul 12, 2017
Decision date	Aug 31, 2017
Days to decision	50 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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