

K161891 HC PrimerNov 21, 2016
133 days to decisionK161891 · Product code: **KLE** · Dental
Source: <https://www.510kdatabase.net/k161891/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Jul 11, 2016
Decision date	Nov 21, 2016
Days to decision	133 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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