

K180649 BeautiCem Veneer KitJun 11, 2018
90 days to decisionK180649 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k180649/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Mar 13, 2018
Decision date	Jun 11, 2018
Days to decision	90 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180649/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 30, 2026