

K131504 UNIVERSAL OPAQUEJul 16, 2013
53 days to decisionK131504 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k131504/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	May 24, 2013
Decision date	Jul 16, 2013
Days to decision	53 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131504/> 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 June 8, 2026