

K181312 GrandioSO x-traAug 22, 2018
97 days to decisionK181312 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k181312/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	May 17, 2018
Decision date	Aug 22, 2018
Days to decision	97 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Voco GmbH
Location	Denver, CO, US
Contact	M. Th. Plaumann
Website	https://www.voco.dental
510(k) history	119 submissions · 119 cleared · 1991-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181312/> 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