

K232050 saremco print BRIDGETECNov 14, 2023
127 days to decisionK232050 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k232050/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Jul 10, 2023
Decision date	Nov 14, 2023
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Saremco Dental AG
Location	Rebstein, CH
Contact	Franca Schmid
510(k) history	4 submissions · 4 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	Bqc Consulting, LLC
Contact	Nevine Erian

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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