

K222581 Stela Automix SystemOct 28, 2022
63 days to decisionK222581 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k222581/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Aug 26, 2022
Decision date	Oct 28, 2022
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sdi Limited
Location	Bayswater, AU
Contact	Quynh Jewell
510(k) history	6 submissions · 6 cleared · 2010-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222581/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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