

K190758 Opus Bulk Fill APS, Opus Bulk Fill Flow APSSep 4, 2019
163 days to decisionK190758 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k190758/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Mar 25, 2019
Decision date	Sep 4, 2019
Days to decision	163 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dentscare Ltda
Location	Joinville, BR
Contact	Roberta Uyara
510(k) history	10 submissions · 10 cleared · 2019-2024

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