

K191385 BRILLIANT COMPONEEROct 29, 2019
159 days to decisionK191385 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k191385/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	May 23, 2019
Decision date	Oct 29, 2019
Days to decision	159 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Coltene/Whaledent AG
Location	New York, NY, US
Contact	Wolfgang Dorner
510(k) history	16 submissions · 16 cleared · 2005-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191385/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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