

**K181500 BRILLIANT Crios**Aug 15, 2018  
69 days to decisionK181500 · Product code: **EBF** · Dental  
Source: <https://www.510kdatabase.net/k181500/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Jun 7, 2018
Decision date	Aug 15, 2018
Days to decision	69 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Coltene/Whaledent AG</b>
Location	New York, NY, US
Contact	Daniel Meier
510(k) history	16 submissions · 16 cleared · 2005-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Emergo Global Consulting, LLC</b>
Contact	Stuart R Goldman

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

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