

**K150218 Fill-Up!**Jun 23, 2015  
144 days to decisionK150218 · Product code: **EBF** · Dental  
Source: <https://www.510kdatabase.net/k150218/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Jan 30, 2015
Decision date	Jun 23, 2015
Days to decision	144 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k150218/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 23, 2026