

**K033773 CONCEPT HP ADD-ON**Jan 15, 2004  
43 days to decisionK033773 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k033773/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Dec 3, 2003
Decision date	Jan 15, 2004
Days to decision	43 days
Third-party review	No
Summary / Statement	Statement
Other names	CONCEPT HP ENAMEL

**APPLICANT**

---

Company	<b>Ivoclar Vivadent, AG</b>
Location	Amherst, NY, US
Contact	DONNA MARIE HARTNETT
510(k) history	31 submissions · 31 cleared · 2004-2022

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k033773/> 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 28, 2026