

**K033760 ONE COAT SE BOND**Jan 23, 2004  
52 days to decisionK033760 · Product code: **KLE** · DentalSource: <https://www.510kdatabase.net/k033760/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Dec 2, 2003
Decision date	Jan 23, 2004
Days to decision	52 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Coltene/Whaledent, Inc.</b>
Location	New York, NY, US
Contact	HENRY J VOGELSTEIN
Website	<a href="https://ap.coltene.com/">https://ap.coltene.com/</a>
510(k) history	21 submissions · 21 cleared · 1991-2007

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k033760/> 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 26, 2026