

K031752 COLTOSOL FAug 5, 2003
61 days to decisionK031752 · Product code: **EMA** · Dental
Source: <https://www.510kdatabase.net/k031752/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Cement, Dental (EMA) |
| Date received | Jun 5, 2003 |
| Decision date | Aug 5, 2003 |
| Days to decision | 61 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Coltene/Whaledent, Inc. |
| Location | New York, NY, US |
| Contact | H.J. VOGELSTEIN |
| Website | https://ap.coltene.com/ |
| 510(k) history | 21 submissions · 21 cleared · 1991-2007 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k031752/> Data sourced from FDA 510(k) public records (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. - Generated June 26, 2026