

**K964808 SPETEMP**Feb 26, 1997  
89 days to decisionK964808 · Product code: **EMA** · Dental  
Source: <https://www.510kdatabase.net/k964808/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Cement, Dental (EMA)               |
| Date received         | Nov 29, 1996                       |
| Decision date         | Feb 26, 1997                       |
| Days to decision      | 89 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Ultradent Products, Inc.</b>                                   |
| Location       | Salt Lake City, UT, US  |
| Contact        | CHESTER MCCCCOY   |
| Website        | <a href="https://www.ultradent.com">https://www.ultradent.com</a> |
| 510(k) history | 103 submissions · 103 cleared · 1992-2026                         |

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964808/> 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