

**K010176 CALEX CONDITIONER**Mar 27, 2001  
68 days to decisionK010176 · Product code: **EJK** · DentalSource: <https://www.510kdatabase.net/k010176/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)     |
| Submission type       | Traditional                            |
| Device classification | Liner, Cavity, Calcium Hydroxide (EJK) |
| Date received         | Jan 18, 2001                           |
| Decision date         | Mar 27, 2001                           |
| Days to decision      | 68 days                                |
| Third-party review    | No                                     |
| Summary / Statement   | Statement                              |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Stephen M Koral, Dmd</b>           |
| Location       | Boulder, CO, US                       |
| Contact        | STEPHEN M KORAL                       |
| 510(k) history | 2 submissions · 2 cleared · 2001-2002 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010176/> 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 July 2, 2026