

**K894282 FIRST IMPRESSION TM**Dec 22, 1989  
182 days to decisionK894282 · Product code: **ELW** · Dental  
Source: <https://www.510kdatabase.net/k894282/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Material, Impression (ELW)         |
| Date received         | Jun 23, 1989                       |
| Decision date         | Dec 22, 1989                       |
| Days to decision      | 182 days                           |
| Third-party review    | No                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Coe Laboratories, Inc.</b>           |
| Location       | Mchenry, IL, US                         |
| Contact        | RICHARD DEMKE                           |
| 510(k) history | 20 submissions · 20 cleared · 1976-1990 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k894282/>; 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 4, 2026