

**K850036 COLTENE PRECISE**Feb 8, 1985  
32 days to decisionK850036 · Product code: **ELW** · Dental  
Source: <https://www.510kdatabase.net/k850036/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Material, Impression (ELW)         |
| Date received         | Jan 7, 1985                        |
| Decision date         | Feb 8, 1985                        |
| Days to decision      | 32 days                            |
| Third-party review    | No                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Coltene, Inc.</b>                    |
| Location       | Mchenry, IL, US                         |
| Contact        | ROBERT W BAUER                          |
| 510(k) history | 13 submissions · 13 cleared · 1981-1990 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k850036/>; 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