

**K973694 PROVIL NOVO**Nov 24, 1997  
59 days to decisionK973694 · Product code: **ELW** · Dental  
Source: <https://www.510kdatabase.net/k973694/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Material, Impression (ELW)         |
| Date received         | Sep 26, 1997                       |
| Decision date         | Nov 24, 1997                       |
| Days to decision      | 59 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---|
| Company        | <b>Heraeus Kulzer, Inc.</b>               |
| Location       | Elkhart, IN, US                           |
| Contact        | CHERYL V ZIMMERMAN                        |
| 510(k) history | 145 submissions · 145 cleared · 1988-2009 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k973694/> 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 May 20, 2026