

**K043504 PALAIMPACT**Jan 28, 2005  
39 days to decisionK043504 · Product code: **EBI** · DentalSource: <https://www.510kdatabase.net/k043504/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                  |
| Submission type       | Traditional   |
| Device classification | Resin, Denture, Relining, Repairing, Rebasing (EBI) |
| Date received         | Dec 20, 2004  |
| Decision date         | Jan 28, 2005  |
| Days to decision      | 39 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/k043504/> 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