

**K943378 IMPLEX CEMENT RESTRICTOR SYSTEM**Sep 23, 1994  
72 days to decisionK943378 · Product code: **LZN** · Orthopedic  
Source: <https://www.510kdatabase.net/k943378/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Cement Obturator (LZN)             |
| Date received         | Jul 13, 1994                       |
| Decision date         | Sep 23, 1994                       |
| Days to decision      | 72 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Implex Corp.</b>                     |
| Location       | Allendale, NJ, US                       |
| Contact        | DAVID W SCHLERT                         |
| 510(k) history | 65 submissions · 61 cleared · 1993-2005 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k943378/> 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 14, 2026