

**K992403 MRP-TITAN**Jan 21, 2000  
186 days to decisionK992403 · Product code: **LZO** · Orthopedic  
Source: <https://www.510kdatabase.net/k992403/>**SUBMISSION DETAILS**

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|                       |                                                                                                    |
|-----------------------|----------------------------------------------------------------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)                                                                 |
| Submission type       | Traditional                                                                                        |
| Device classification | Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO) |
| Date received         | Jul 19, 1999                                                                                       |
| Decision date         | Jan 21, 2000                                                                                       |
| Days to decision      | 186 days                                                                                           |
| Third-party review    | No                                                                                                 |
| Summary / Statement   | Summary                                                                                            |

**APPLICANT**

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|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Rotec Medizintechnik GmbH</b>      |
| Location       | Weisendorf, DE                        |
| Contact        | ING ULRICH HOLZWARTH                  |
| 510(k) history | 2 submissions · 2 cleared · 2000-2000 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k992403/> 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 21, 2026