

**K182872 LINK GEMINI SL Total Knee System**Apr 3, 2019  
173 days to decisionK182872 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k182872/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional  |
| Device classification | Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH) |
| Date received         | Oct 12, 2018   |
| Decision date         | Apr 3, 2019  |
| Days to decision      | 173 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Waldemar Link GmbH &amp; Co. KG</b>  |
| Location       | Mchenry, IL, US                         |
| Contact        | Andre von Malotki                       |
| 510(k) history | 42 submissions · 42 cleared · 1978-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182872/> 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 16, 2026