

**K001548 MODULAR ROTATING HINGE KNEE CROSSOVER  
TIBIAL BEARING COMPONENTS**Jun 7, 2000  
20 days to decisionK001548 · Product code: **KRO** · Orthopedic  
Source: <https://www.510kdatabase.net/k001548/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Special  |
| Device classification | Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/polymer (KRO) |
| Date received         | May 18, 2000   |
| Decision date         | Jun 7, 2000  |
| Days to decision      | 20 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Howmedica Osteonics Corp.</b>          |
| Location       | Allendale, NJ, US                         |
| Contact        | JENNIFER A DAUDELIN                       |
| 510(k) history | 288 submissions · 288 cleared · 1999-2020 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k001548/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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