

K991143 MAGNA-ROM 21 KNEE SYSTEEMJun 11, 1999
67 days to decisionK991143 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k991143/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH) |
| Date received | Apr 5, 1999 |
| Decision date | Jun 11, 1999 |
| Days to decision | 67 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Sulzer Orthopedics, Inc. |
| Location | Austin, TX, US |
| Contact | SHAWAWN PARDUHN |
| 510(k) history | 45 submissions · 41 cleared · 1997-2002 |

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