

**K971189 P.F.C. SIGMA KNEE SYSTEM (SIZE 1.5)**Jul 17, 1997  
107 days to decisionK971189 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k971189/>**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         | Apr 1, 1997  |
| Decision date         | Jul 17, 1997   |
| Days to decision      | 107 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Johnson &amp; Johnson Professionals, Inc.</b>      |
| Location       | Raynham, MA, US                                       |
| Contact        | JOHN FERROS   |
| Website        | <a href="https://www.jnj.com">https://www.jnj.com</a> |
| 510(k) history | 206 submissions · 184 cleared · 1976-2000             |

Johnson & Johnson Professionals, Inc. is a medical device company based in Raynham, Massachusetts. The company specializes in surgical and orthopedic devices. The company has received FDA 510(k) clearances from total submissions between 1976 and 2000. Orthopedic devices and neurosurgical instruments represent core product categories. Notable cleared devices include hip and elbow prostheses, programmable valve systems, and aneurysm clips. The company is inactive and represents a historical regulatory record with no submissions in more than two decades. Explore the complete...

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