

K943462 DARWIN KNEE SYSTEMDec 21, 1994
156 days to decisionK943462 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k943462/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Jul 18, 1994
Decision date	Dec 21, 1994
Days to decision	156 days
Third-party review	No

APPLICANT

Company	Johnson & Johnson Professionals, Inc.
Location	Raynham, MA, US
Contact	JOHN D FERROS
Website	https://www.jnj.com
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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Device record: <https://www.510kdatabase.net/k943462/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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