FDA 510(k) Premarket Notification

CLEARED

K964795 CEMENTED CALCAR REPLACEMENT FEMORAL STEM

Feb 19, 1997
82 days to decision

K964795 · Product code: **JDI** · Orthopedic
Source: https://www.510kdatabase.net/k964795/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Nov 29, 1996
Decision date	Feb 19, 1997
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Johnson & Johnson Professionals, Inc.**
Location	Raynham, MA, US
Contact	DEANA M BOUSHELL
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...