

K972435 ULTIMA AND ULTIMA LX CEMENTED FEMORAL STEMSep 11, 1997
73 days to decisionK972435 · Product code: **JDI** · Orthopedic
Source: <https://www.510kdatabase.net/k972435/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Jun 30, 1997
Decision date	Sep 11, 1997
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Johnson & Johnson Professionals, Inc.
Location	Raynham, MA, US
Contact	MARY E GRAY
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...
