FDA 510(k) Premarket Notification

CLEARED

K113296 ZMR HIP SYSTEM KWZ-PROSTHESIS, HIP, CONSTRAINED, CEMENTED OR UNCEMENTED, METAL/POLYMER

Sep 14, 2012
311 days to decision

K113296 · Product code: **LPH** · Orthopedic
Source: https://www.510kdatabase.net/k113296/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	Nov 8, 2011
Decision date	Sep 14, 2012
Days to decision	311 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Zimmer, Inc.**
Location	Warsaw, IN, US
Contact	DANIEL J WILLIMAN
Website	https://www.zimmerbiomet.com
510(k) history	373 submissions · 352 cleared · 1976-2026

Zimmer, Inc. is a leading orthopedic medical device manufacturer based in Warsaw, US. The company specializes in innovative surgical implants and trauma solutions. Zimmer, Inc. maintains a strong FDA 510(k) regulatory record with cleared devices from total submissions since 1976. Orthopedic devices represent approximately 90% of the company's submission portfolio. The company remains actively engaged in product development, with the latest FDA 510(k) clearance in 2026. Recent cleared devices reflect the company's focus on joint reconstruction and trauma fixation. Notable ...