FDA 510(k) Premarket Notification

CLEARED

K101229 LONGEVITY IT HIGHLY CROSSLINKED POLYETHYLENE ELEVATED LINERS, CONTINUUM ACETABULAR SYSTEM AND TRILOGY INTEGRATED TAPER

Dec 3, 2010
214 days to decision

K101229 · Product code: **LPH** · Orthopedic
Source: https://www.510kdatabase.net/k101229/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	May 3, 2010
Decision date	Dec 3, 2010
Days to decision	214 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Zimmer, Inc.**
Location	Warsaw, IN, US
Contact	REBECCA BROOKS
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 ...