FDA 510(k) Premarket Notification

K120370 VIVACIT-E VITAMIN E HIGHLY CROSSLINKED POLYETHYLENE LINERS

CLEARED

Jun 4, 2012
119 days to decision

K120370 · Product code: **OQG** · Orthopedic
Source: https://www.510kdatabase.net/k120370/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hip Prosthesis, Semi-constrained, Cemented, Metal/polymer, + Additive, Porous, Uncemented (OQG)
Date received	Feb 6, 2012
Decision date	Jun 4, 2012
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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