FDA 510(k) Premarket Notification

CLEARED

K183136 Zimmer Segmental System Proximal Femoral Component

Jan 30, 2019
78 days to decision

K183136 · Product code: **LZO** · Orthopedic
Source: https://www.510kdatabase.net/k183136/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	Nov 13, 2018
Decision date	Jan 30, 2019
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Zimmer, Inc.**
Location	Warsaw, IN, US
Contact	Jason Heckaman
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 ...