

K190656 Dual Mobility - Longevity and Vivacit-E Polyethylene Hip Bearings

Dec 6, 2019
267 days to decisionK190656 · Product code: LPH · Orthopedic
Source: <https://www.510kdatabase.net/k190656/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	Mar 14, 2019
Decision date	Dec 6, 2019
Days to decision	267 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Zimmer, Inc.
Location	Warsaw, IN, US
Contact	Charles Neitzel
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 ...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k190656/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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