

K190660 G7 Acetabular System Longevity Highly Crosslinked Polyethylene, G7 Acetabular System Vivacit-E Vitamin E Highly Crosslinked Polyethylene

Dec 5, 2019
266 days to decision

K190660 · Product code: LPH · Orthopedic
Source: <https://www.510kdatabase.net/k190660/>

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 5, 2019
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Zimmer, Inc.
Location	Warsaw, IN, US
Contact	Mary Wentorf
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 ...