

K182048 Avenir Complete Hip System

Dec 7, 2018
129 days to decisionK182048 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k182048/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	Jul 31, 2018
Decision date	Dec 7, 2018
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Zimmer, Inc.
Location	Warsaw, IN, US
Contact	Rebecca D Noftz
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 ...