FDA 510(k) Premarket Notification

K912263 HA ANATOMIC HIP PROSTH W/ TI-NIDIUM SURF HARD PROC

CLEARED

Aug 29, 1991
99 days to decision

K912263 · Product code: **MEH** · Orthopedic
Source: https://www.510kdatabase.net/k912263/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Uncemented, Metal / Polymer, Non-porous, Calcium Phosphate (MEH)
Date received	May 22, 1991
Decision date	Aug 29, 1991
Days to decision	99 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Zimmer, Inc.**
Location	Warsaw, IN, US
Contact	CHRISTOPHER PETERSON
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 ...