FDA 510(k) Premarket Notification

CLEARED

K041100 NEXGEN POROUS, HA/TCP, UNCEMENTED FEMORAL AND TIBIAL BASEPLATE COMPONENTS

Oct 29, 2004
185 days to decision

K041100 · Product code: **MBH** · Orthopedic
Source: https://www.510kdatabase.net/k041100/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Patello/femorotibial, Semi-constrained, Uncemented, Porous, Coated, Polymer/metal/polymer (MBH)
Date received	Apr 27, 2004
Decision date	Oct 29, 2004
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Zimmer, Inc.**
Location	Warsaw, IN, US
Contact	DALENE T BINKLEY
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 ...