FDA 510(k) Premarket Notification

K261683 Augment Off-Axis Instrument System

CLEARED

Jun 16, 2026
26 days to decision

K261683 · Product code: **PHX** · Orthopedic
Source: https://www.510kdatabase.net/k261683/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	May 21, 2026
Decision date	Jun 16, 2026
Days to decision	26 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zimmer, Inc.**
Location	Warsaw, IN, US
Contact	Eric Van Horn
Website	https://www.zimmerbiomet.com
510(k) history	376 submissions · 355 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 ...