FDA 510(k) Premarket Notification

K142442 MAGNA-FX AND MINI MAGNA-FX CANNULATED SCREW FIXATION SYSTEM

CLEARED

Oct 3, 2014
31 days to decision

K142442 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k142442/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Sep 2, 2014
Decision date	Oct 3, 2014
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Zimmer, Inc.**
Location	Warsaw, IN, US
Contact	PATRICK MCCULLAGH
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 ...