

K243571 Trabecular Metal Acetabular Revision System, Acetabular Liners and Constrained Liners

Jul 31, 2025
255 days to decision

K243571 · Product code: JDI · Orthopedic
Source: <https://www.510kdatabase.net/k243571/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Nov 18, 2024
Decision date	Jul 31, 2025
Days to decision	255 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zimmer Biomet
Location	Warsaw, IN, US
Contact	Sean Gleason
Website	http://www.zimmer.com/
510(k) history	5 submissions · 5 cleared · 2024-2025

Zimmer Biomet is a global leader in orthopedic innovations with a manufacturing facility in Warsaw, US. The company develops and markets surgical implants, instruments, and technologies for joint reconstruction and orthopedic care. The company has received FDA 510(k) clearances from total submissions. All submissions focus on Orthopedic devices. The company's first clearance was in 2024, with the most recent in 2025, demonstrating active regulatory engagement. Recent cleared devices include knee systems such as the Persona Partial Knee and Persona Personalized Knee System...