

K250834 Zimmer Biomet Ceramic Heads (22.2mm diameter)Apr 18, 2025
30 days to decisionK250834 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k250834/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	Mar 19, 2025
Decision date	Apr 18, 2025
Days to decision	30 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...