FDA 510(k) Premarket Notification

K251834 Persona Partial Knee

CLEARED

Aug 15, 2025
60 days to decision

K251834 · Product code: **HSX** · Orthopedic
Source: https://www.510kdatabase.net/k251834/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Non-constrained, Cemented, Metal/polymer (HSX)
Date received	Jun 16, 2025
Decision date	Aug 15, 2025
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zimmer Biomet**
Location	Warsaw, IN, US
Contact	Courtney Williams
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...