FDA 510(k) Premarket Notification

K241059 Pantheon Proximal Femur Reconstruction (PFR) System

CLEARED

Jan 13, 2025
270 days to decision

K241059 · Product code: **LPH** · Orthopedic
Source: https://www.510kdatabase.net/k241059/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	Apr 18, 2024
Decision date	Jan 13, 2025
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Adler Ortho S.P.A**
Location	Cormano (Mi), IT
Contact	Davide Cremascoli
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	Mehdi Kazemzadeh-Narbat

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov