

**K241059 Pantheon Proximal Femur Reconstruction (PFR) System**Jan 13, 2025  
270 days to decisionK241059 · 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	<b>Adler Ortho S.P.A</b>
Location	Cormano (Mi), IT
Contact	Davide Cremascoli
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Mcra, LLC</b>
Contact	Mehdi Kazemzadeh-Narbat

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

---

510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241059/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026