

K241636 MobileLink Acetabular Cup System - Line Extension (Multiple)

Nov 8, 2024
155 days to decisionK241636 · Product code: LPH · Orthopedic
Source: <https://www.510kdatabase.net/k241636/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	Jun 6, 2024
Decision date	Nov 8, 2024
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Waldemar Link GmbH & Co. KG
Location	Mchenry, IL, US
Contact	Stefanie Fuchs
510(k) history	42 submissions · 42 cleared · 1978-2025

REGULATORY CONSULTANT

Consulting firm	LinkBio Corp.
Contact	Luisa Moncada

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.netDevice record: <https://www.510kdatabase.net/k241636/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026