

K250375 Allure Hip Stem and Intramedullary PlugsNov 5, 2025
268 days to decisionK250375 · Product code: **MEH** · Orthopedic
Source: <https://www.510kdatabase.net/k250375/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Uncemented, Metal / Polymer, Non-porous, Calcium Phosphate (MEH)
Date received	Feb 10, 2025
Decision date	Nov 5, 2025
Days to decision	268 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	Pia Müller
510(k) history	42 submissions · 42 cleared · 1978-2025

REGULATORY CONSULTANT

Consulting firm	LinkBio Corp.
Contact	Terry Powell

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/k250375/> 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 14, 2026