

K261009 MobileLink Acetabular Cup System – 40mm ID Inserts
(various)

Jul 6, 2026
102 days to decision

K261009 · Product code: LZO · Orthopedic
Source: <https://www.510kdatabase.net/k261009/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	Mar 26, 2026
Decision date	Jul 6, 2026
Days to decision	102 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	43 submissions · 43 cleared · 1978-2026

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)