K211567 BiMobile Instruments (for BiMobile Dual Mobility System)

CLEARED

Jun 3, 2022
378 days to decision

K211567 · Product code: **LZO** · Orthopedic
Source: https://www.510kdatabase.net/k211567/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	May 21, 2021
Decision date	Jun 3, 2022
Days to decision	378 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	Stefani Fuchs

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