

K190535 BiMobile Dual Mobility System - E-Dur Inserts

Aug 6, 2019
155 days to decision

K190535 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k190535/>

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 4, 2019
Decision date	Aug 6, 2019
Days to decision	155 days
Third-party review	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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k190535/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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