FDA 510(k) Premarket Notification

K190535 BiMobile Dual Mobility System - E-Dur Inserts

CLEARED

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