FDA 510(k) Premarket Notification

CLEARED

K211768 LINK Endo-Model Knee System, Femoral Segments (Augments), UHMWPE

Jun 30, 2021
22 days to decision

K211768 · Product code: **KRO** · Orthopedic
Source: https://www.510kdatabase.net/k211768/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/polymer (KRO)
Date received	Jun 8, 2021
Decision date	Jun 30, 2021
Days to decision	22 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	Terry Sheridan Powell

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