

K212742 GEMINI SL Total Knee System, Endo-Model Knee System, and Sled Knee System with LINK PorEx (TiNbN) inhouse coatingSep 16, 2021
17 days to decisionK212742 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k212742/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Aug 30, 2021
Decision date	Sep 16, 2021
Days to decision	17 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	Lydia Ditter
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](https://accessdata.fda.gov)

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