

K191755 SPAR-K Instruments (for use with Gemini SL Total Knee System)Jul 18, 2019
17 days to decisionK191755 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k191755/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Jul 1, 2019
Decision date	Jul 18, 2019
Days to decision	17 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.netDevice record: <https://www.510kdatabase.net/k191755/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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