

K212034 LOSPA TKR SystemDec 9, 2021
163 days to decisionK212034 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k212034/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Jun 29, 2021
Decision date	Dec 9, 2021
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Corentec Co., Ltd.
Location	West Cadwell, NJ, US
Contact	Seungri Kim
510(k) history	33 submissions · 33 cleared · 2010-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212034/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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