

K234011 AMF TT ConesJan 18, 2024
30 days to decisionK234011 · Product code: **JWH** · Orthopedic
Source: <https://www.510kdatabase.net/k234011/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Dec 19, 2023
Decision date	Jan 18, 2024
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Lima Corporate S.P.A.
Location	Winona Lake, IN, US
Contact	Michela Zanotto
510(k) history	64 submissions · 64 cleared · 2011-2026

REGULATORY CONSULTANT

Consulting firm	Lima U.S.A., Inc.
Contact	Newman Kenneth

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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