

**K213381 Physica system**Dec 17, 2021  
65 days to decisionK213381 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k213381/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Oct 13, 2021
Decision date	Dec 17, 2021
Days to decision	65 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lima Corporate S.P.A.</b>
Location	Winona Lake, IN, US
Contact	Ilaria Giannuzzi
510(k) history	64 submissions · 64 cleared · 2011-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Lima U.S.A., Inc.</b>
Contact	Lacey Harbour

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213381/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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