

**K210554 Physica system**Apr 6, 2021  
40 days to decisionK210554 · Product code: **MBH** · Orthopedic  
Source: <https://www.510kdatabase.net/k210554/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patello/femorotibial, Semi-constrained, Uncemented, Porous, Coated, Polymer/metal/polymer (MBH)
Date received	Feb 25, 2021
Decision date	Apr 6, 2021
Days to decision	40 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	Giuseppe Valenti
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/k210554/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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