

**K233712 PRIMA Humeral System**Jan 11, 2024  
52 days to decisionK233712 · Product code: **MBF** · Orthopedic  
Source: <https://www.510kdatabase.net/k233712/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer, Uncemented (MBF)
Date received	Nov 20, 2023
Decision date	Jan 11, 2024
Days to decision	52 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	PRIMA TT Glenoid

**APPLICANT**

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Company	<b>Lima Corporate S.P.A.</b>
Location	Winona Lake, IN, US
Contact	Michela Zanotto
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	Kenneth Newman

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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