

**K222427 PRIMA TT Glenoid**Oct 6, 2022  
56 days to decisionK222427 · Product code: **MBF** · Orthopedic  
Source: <https://www.510kdatabase.net/k222427/>**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         | Aug 11, 2022  |
| Decision date         | Oct 6, 2022   |
| Days to decision      | 56 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        | 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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222427/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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