

**K181362 TEMA Elbow System**Feb 16, 2019  
269 days to decisionK181362 · Product code: **JDC** · Orthopedic  
Source: <https://www.510kdatabase.net/k181362/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Elbow, Constrained, Cemented (JDC)
Date received	May 23, 2018
Decision date	Feb 16, 2019
Days to decision	269 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181362/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 16, 2026