

**K160011 H-Max S stem**Aug 22, 2016  
231 days to decisionK160011 · Product code: **MEH** · Orthopedic  
Source: <https://www.510kdatabase.net/k160011/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Uncemented, Metal / Polymer, Non-porous, Calcium Phosphate (MEH)
Date received	Jan 4, 2016
Decision date	Aug 22, 2016
Days to decision	231 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	EMANUELE BUTTAZZONI
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/k160011/> 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 17, 2026