

K112091 H-MAX S FEMORAL STEMS, MODULAR FEMORAL HEADS, CEMENTED CUPS, LOCK BIPOLAR HEADSNov 9, 2012
477 days to decisionK112091 · Product code: **MEH** · Orthopedic
Source: <https://www.510kdatabase.net/k112091/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Uncemented, Metal / Polymer, Non-porous, Calcium Phosphate (MEH)
Date received	Jul 21, 2011
Decision date	Nov 9, 2012
Days to decision	477 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Lima Corporate S.P.A.
Location	Winona Lake, IN, US
Contact	CHERYL HASTINGS
510(k) history	64 submissions · 64 cleared · 2011-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k112091/>, Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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