

K161635 AMIStem-H Proximal CoatingMar 31, 2017
290 days to decisionK161635 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k161635/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	Jun 14, 2016
Decision date	Mar 31, 2017
Days to decision	290 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medacta International S.A.
Location	Castel San Pietro, CH
Contact	STEFANO BAJ
Website	https://www.medacta.com
510(k) history	164 submissions · 164 cleared · 2008-2026

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