

K193433 AMIStem-CJan 9, 2020
30 days to decisionK193433 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k193433/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	Dec 10, 2019
Decision date	Jan 9, 2020
Days to decision	30 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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