

**K192126 AMIStem-P Short Neck**Nov 22, 2019  
108 days to decisionK192126 · Product code: **LZO** · Orthopedic  
Source: <https://www.510kdatabase.net/k192126/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	Aug 6, 2019
Decision date	Nov 22, 2019
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medacta International S.A.</b>
Location	Castel San Pietro, CH
Contact	Stefano Baj
Website	<a href="https://www.medacta.com">https://www.medacta.com</a>
510(k) history	164 submissions · 164 cleared · 2008-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192126/> 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