

**K121011 AMISTEM AND QUADRA - LINE EXTENSION**Jun 8, 2012  
66 days to decisionK121011 · Product code: **LZO** · Orthopedic  
Source: <https://www.510kdatabase.net/k121011/>**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	Apr 3, 2012
Decision date	Jun 8, 2012
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Medacta International</b>
Location	San Diego, CA, US
Contact	ADAM GROSS
510(k) history	39 submissions · 39 cleared · 2011-2016

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121011/> 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