

**K070928 CERAMIC BALL HEADS, 28, 32 AND 36 MM**Aug 1, 2007  
120 days to decisionK070928 · Product code: **LZO** · Orthopedic  
Source: <https://www.510kdatabase.net/k070928/>**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	Apr 3, 2007
Decision date	Aug 1, 2007
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Plus Orthopedics AG</b>
Location	Norfolk, MA, US
Contact	PAMELA J WEAGRAFF
510(k) history	5 submissions · 5 cleared · 2006-2007

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k070928/> 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 19, 2026