

**K082991 BIOLOX DELTA CERAMIC FEMORAL HEAD**Nov 20, 2008  
44 days to decisionK082991 · Product code: **LZO** · Orthopedic  
Source: <https://www.510kdatabase.net/k082991/>**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	Oct 7, 2008
Decision date	Nov 20, 2008
Days to decision	44 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Aesculap Implant Systems, Inc.</b>
Location	Center Valley, PA, US
Contact	KATHY A RACOSKY
510(k) history	22 submissions · 22 cleared · 2007-2016

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082991/> 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