

K090299 BIOLOX OPTION CERAMIC FEMORAL HEAD AND METHA XL HEADSApr 24, 2009
77 days to decisionK090299 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k090299/>**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	Feb 6, 2009
Decision date	Apr 24, 2009
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Aesculap Implant Systems
Location	Center Valley, PA, US
Contact	KATHY A RACOSKY
510(k) history	7 submissions · 7 cleared · 2007-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k090299/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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