

**K192416 BIOLOX Delta Ceramic Femoral Heads, BIOLOX Option Ceramic Femoral Head System**Oct 1, 2019  
27 days to decisionK192416 · Product code: **LZO** · Orthopedic  
Source: <https://www.510kdatabase.net/k192416/>**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	Sep 4, 2019
Decision date	Oct 1, 2019
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zimmer GmbH</b>
Location	Warsaw, IN, US
Contact	Roberto Tommasini
510(k) history	43 submissions · 43 cleared · 2004-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192416/>; 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