

**K243809 BioloX® Delta Revision heads**Mar 4, 2025  
83 days to decisionK243809 · Product code: **LZO** · Orthopedic  
Source: <https://www.510kdatabase.net/k243809/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	Dec 11, 2024
Decision date	Mar 4, 2025
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Limacorporate</b>
Location	San Daniele Del Friuli, IT
Contact	Alessia Collarini
Website	<a href="http://www.limacorporate.com/">http://www.limacorporate.com/</a>
510(k) history	4 submissions · 4 cleared · 2019-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Enovis</b>
Contact	Alessia Collarini

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243809/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026