FDA 510(k) Premarket Notification

K243809 Biolox® Delta Revision heads

CLEARED

Mar 4, 2025
83 days to decision

K243809 · Product code: **LZO** · Orthopedic
Source: https://www.510kdatabase.net/k243809/

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	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

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

REGULATORY CONSULTANT

Consulting firm	**Enovis**
Contact	Alessia Collarini

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov