

K243043 Origin™ Cemented Hip StemMay 2, 2025
217 days to decisionK243043 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k243043/>**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	Sep 27, 2024
Decision date	May 2, 2025
Days to decision	217 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Signature Orthopaedics Pty, Ltd.
Location	Lane Cove, AU
Contact	Declan Brazil
Website	https://www.signatureortho.com.au
510(k) history	44 submissions · 44 cleared · 2012-2026

Signature Orthopaedics Pty, Ltd. is an Orthopedic device manufacturer based in Lane Cove, Australia. The company designs, prototypes, and manufactures innovative surgical implants and instruments. Signature Orthopaedics has achieved FDA 510(k) clearances from total submissions since 2012. All submissions have focused on Orthopedic devices, including hip stems, knee systems, spinal screws, and soft tissue anchors. The company's latest clearance in 2026 demonstrates continued regulatory activity and product innovation. The company operates in-house capabilities for design, ...

REGULATORY CONSULTANT

Consulting firm	BioVera, Inc.
Contact	Robert Poggie

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

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Device record: <https://www.510kdatabase.net/k243043/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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