

**K190704 Signature Ceramic Femoral Head**Aug 28, 2019  
163 days to decisionK190704 · Product code: **LZO** · Orthopedic  
Source: <https://www.510kdatabase.net/k190704/>**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	Mar 18, 2019
Decision date	Aug 28, 2019
Days to decision	163 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Signature Orthopaedics Pty, Ltd.</b>
Location	Lane Cove, AU
Contact	Declan Brazil
Website	<a href="https://www.signatureortho.com.au">https://www.signatureortho.com.au</a>
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, ...

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