

K161155 Origin Coxa Vara Hip StemJul 19, 2016
85 days to decisionK161155 · Product code: **MEH** · Orthopedic
Source: <https://www.510kdatabase.net/k161155/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Uncemented, Metal / Polymer, Non-porous, Calcium Phosphate (MEH)
Date received	Apr 25, 2016
Decision date	Jul 19, 2016
Days to decision	85 days
Third-party review	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, ...
