

K243162 World LinerNov 25, 2024
56 days to decisionK243162 · Product code: **MEH** · Orthopedic
Source: <https://www.510kdatabase.net/k243162/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Semi-constrained, Uncemented, Metal / Polymer, Non-porous, Calcium Phosphate (MEH)
Date received	Sep 30, 2024
Decision date	Nov 25, 2024
Days to decision	56 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, ...