

**K181340 Cemented TSI Hip Stem**Feb 11, 2019  
266 days to decisionK181340 · Product code: **JDI** · Orthopedic  
Source: <https://www.510kdatabase.net/k181340/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	May 21, 2018
Decision date	Feb 11, 2019
Days to decision	266 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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