

**K243029 Origin™ TT Stem**Mar 11, 2025  
165 days to decisionK243029 · Product code: **LZO** · Orthopedic  
Source: <https://www.510kdatabase.net/k243029/>**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         | Sep 27, 2024   |
| Decision date         | Mar 11, 2025   |
| Days to decision      | 165 days   |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | 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, ...

**REGULATORY CONSULTANT**

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|-----------------|----------------------|
| Consulting firm | <b>BioVera, Inc.</b> |
| 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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k243029/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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