

K230655 PEEK RCI ScrewMay 3, 2023
55 days to decisionK230655 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k230655/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Fastener, Fixation, Nondegradable, Soft Tissue (MBI) |
| Date received | Mar 9, 2023 |
| Decision date | May 3, 2023 |
| Days to decision | 55 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | Bio-Composite Screw; Signaloc Screw |

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, ...