

K163625 NOOSA Anterior Lumbar Plate SystemAug 11, 2017
232 days to decisionK163625 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k163625/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Dec 22, 2016
Decision date	Aug 11, 2017
Days to decision	232 days
Third-party review	No
Summary / Statement	Summary
Other names	NAMBUCCA Anterior Lumbar Plate System; CAIRNS Anterior Lumbar Plate System

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, ...