

K243980 ARVIS Surgical Navigation SystemMar 21, 2025
88 days to decisionK243980 · Product code: **SBF** · Orthopedic
Source: <https://www.510kdatabase.net/k243980/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Augmented Reality (SBF)
Date received	Dec 23, 2024
Decision date	Mar 21, 2025
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kico Knee Innovation Company Pty Limited
Location	Pymble, AU
Contact	Ryan Matthew
510(k) history	4 submissions · 4 cleared · 2017-2025

REGULATORY CONSULTANT

Consulting firm	Stefanie Michele Auf Der Mauer Asmuss
Contact	Stefanie Auf der Mauer

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243980/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026