FDA 510(k) Premarket Notification

K243950 ARVIS® Shoulder

CLEARED

Jan 13, 2025
21 days to decision

K243950 · Product code: **SBF** · Orthopedic
Source: https://www.510kdatabase.net/k243950/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Augmented Reality (SBF)
Date received	Dec 23, 2024
Decision date	Jan 13, 2025
Days to decision	21 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Kico Knee Innovation Company Pty, Ltd.**
Location	Frenchs Forest, AU
Contact	Ryan Matthew
510(k) history	2 submissions · 2 cleared · 2024-2025

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