FDA 510(k) Premarket Notification

CLEARED

K252524 Quadsense (Quadsense and Quadsense Pro)

Sep 9, 2025
29 days to decision

K252524 · Product code: **ONN** · Orthopedic
Source: https://www.510kdatabase.net/k252524/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intraoperative Orthopedic Joint Assessment Aid (ONN)
Date received	Aug 11, 2025
Decision date	Sep 9, 2025
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Eventum Orthopaedics, Ltd.**
Location	Leeds, GB
Contact	John Naybour
510(k) history	2 submissions · 2 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Kelliann Payne

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov