

K241298 QUADSENSEOct 4, 2024
149 days to decisionK241298 · Product code: **ONN** · Orthopedic
Source: <https://www.510kdatabase.net/k241298/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intraoperative Orthopedic Joint Assessment Aid (ONN)
Date received	May 8, 2024
Decision date	Oct 4, 2024
Days to decision	149 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

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