

K253764 ENOS Software Guided External Fixation SystemFeb 26, 2026
93 days to decisionK253764 · Product code: **OSN** · Orthopedic
Source: <https://www.510kdatabase.net/k253764/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Software For Diagnosis/treatment (OSN)
Date received	Nov 25, 2025
Decision date	Feb 26, 2026
Days to decision	93 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Disior, Ltd.
Location	Helsinki Uusimaa, FL, US
Contact	Aarno Jussila
510(k) history	6 submissions · 6 cleared · 2021-2026

REGULATORY CONSULTANT

Consulting firm	Paragon 28, Inc.
Contact	Edward Wells-Spicer

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

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