

K261113 Op.n™ Spine Navigation and Robotic Guidance

Jul 22, 2026
110 days to decision

K261113 · Product code: OLO · Orthopedic
Source: <https://www.510kdatabase.net/k261113/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Apr 3, 2026
Decision date	Jul 22, 2026
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ecential Robotics
Location	Gieres, FR
Contact	Elodie Bouillet
510(k) history	7 submissions · 7 cleared · 2022-2026