

K230195 Neo ADVISE softwareMar 8, 2024
408 days to decisionK230195 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k230195/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jan 25, 2023
Decision date	Mar 8, 2024
Days to decision	408 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Comerge AG
Location	Zurich, CH
Contact	Beat Hugli
510(k) history	2 submissions · 2 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	Confinis AG
Contact	Frederike Bruhschwein-Mandic

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

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