FDA 510(k) Premarket Notification

K230195 Neo ADVISE software

CLEARED

Mar 8, 2024
408 days to decision

K230195 · 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 Hugi
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