

K223649 VERTICALE® Navigation InstrumentsDec 22, 2022
16 days to decisionK223649 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k223649/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Dec 6, 2022
Decision date	Dec 22, 2022
Days to decision	16 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Silony Medical GmbH
Location	Leinfelden-Echterdingen, DE
Contact	Ralf Klabunde
Website	https://silony-medical.com
510(k) history	12 submissions · 12 cleared · 2017-2026

Silony Medical GmbH is a spine surgery device manufacturer specializing in spinal fusion hardware and surgical systems. Founded in 2013 by the Schön Clinic hospital group, the company operates with a manufacturing facility in Leinfelden-Echterdingen, Germany, and maintains a global presence across 20+ countries. The company has received FDA 510(k) clearances from total submissions, with all submissions focused on Orthopedic devices. Silony's regulatory track record spans from 2017 to 2026, demonstrating sustained innovation and market engagement in spinal implant technolo...