

K253921 VERTICALE® Navigation InstrumentsJun 26, 2026
200 days to decisionK253921 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k253921/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Dec 8, 2025
Decision date	Jun 26, 2026
Days to decision	200 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Silony Medical GmbH
Location	Leinfelden-Echterdingen, DE
Contact	David Weckler
Website	https://silony-medical.com
510(k) history	13 submissions · 13 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 technology.
