FDA 510(k) Premarket Notification

K212007 VERTICALE Navigation Instruments

CLEARED

Aug 12, 2021
45 days to decision

K212007 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k212007/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jun 28, 2021
Decision date	Aug 12, 2021
Days to decision	45 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...

REGULATORY CONSULTANT

Consulting firm	**Empirical Testing Corp**
Contact	Nathan Wright

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