FDA 510(k) Premarket Notification

CLEARED

K223806 VERTICALE® Triangular Fixation System

Jul 6, 2023
199 days to decision

K223806 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k223806/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Dec 19, 2022
Decision date	Jul 6, 2023
Days to decision	199 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	**Mcra, LLC**
Contact	Justin Eggleton

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