

K171421 VERTICALE® Posterior Spinal Fixation System/VERTICALE® SystemJan 10, 2018
240 days to decisionK171421 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k171421/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	May 15, 2017
Decision date	Jan 10, 2018
Days to decision	240 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Silony Medical GmbH
Location	Leinfelden-Echterdingen, DE
Contact	Bircan Yilmaz
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...

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Device record: <https://www.510kdatabase.net/k171421/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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