

**K190680 FAVO S-TLIF**Jul 18, 2019  
122 days to decisionK190680 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k190680/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 18, 2019
Decision date	Jul 18, 2019
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Silony Medical GmbH</b>
Location	Leinfelden-Echterdingen, DE
Contact	Melanie Lubjuhn
Website	<a href="https://silony-medical.com">https://silony-medical.com</a>
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 technology.

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