FDA 510(k) Premarket Notification

K181899 ROCCIA® PLIF

CLEARED

Dec 13, 2018
150 days to decision

K181899 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k181899/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 16, 2018
Decision date	Dec 13, 2018
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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