

**K162587 ROCCIA® ACIF**Jan 26, 2017  
132 days to decisionK162587 · Product code: **ODP** · Orthopedic  
Source: <https://www.510kdatabase.net/k162587/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Sep 16, 2016
Decision date	Jan 26, 2017
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Silony Medical GmbH</b>
Location	Leinfelden-Echterdingen, DE
Contact	Bircan YILMAZ
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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