

K182608 Oyster ACIF CageJun 13, 2019
265 days to decisionK182608 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k182608/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Bone Graft, Cervical (ODP) |
| Date received | Sep 21, 2018 |
| Decision date | Jun 13, 2019 |
| Days to decision | 265 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 technology.
