

**K180071 STYLO Interbody Fusion Device**May 3, 2018  
114 days to decisionK180071 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k180071/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jan 9, 2018
Decision date	May 3, 2018
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Legend Spine Technologies</b>
Location	Bethlehem, PA, US
Contact	Gwendolyn DeBoer
510(k) history	2 submissions · 2 cleared · 2018-2019

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Mrc/X, LLC</b>
Contact	Christine Scifert

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180071/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026