

**K131071 STAXX IBL SYSTEM**Aug 20, 2013  
125 days to decisionK131071 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k131071/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Apr 17, 2013
Decision date	Aug 20, 2013
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Spine Wave, Inc.</b>
Location	Shelton, CT, US
Contact	ROAIDA RIZKALLAH
510(k) history	57 submissions · 57 cleared · 2004-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131071/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 17, 2026