

**K031265 SHIRAZ-JAVA SPINAL FIXATION SYSTEM**Oct 9, 2003  
171 days to decisionK031265 · Product code: **MNH** · Orthopedic  
Source: <https://www.510kdatabase.net/k031265/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Apr 21, 2003
Decision date	Oct 9, 2003
Days to decision	171 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Spine Next SA</b>
Location	Queenstown, MD, US
Contact	DIANE JOHNSON
510(k) history	3 submissions · 1 cleared · 2003-2003

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031265/> 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 20, 2026