

**K182771 ISS-JAZZ Screw System and JAZZ CAP SP**Mar 12, 2019  
165 days to decisionK182771 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k182771/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Sep 28, 2018
Decision date	Mar 12, 2019
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Implanet, S.A.</b>
Location	Philedelphia, PA, US
Contact	Fabienne Larquey Cadriere
510(k) history	15 submissions · 15 cleared · 2012-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182771/> 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 27, 2026