

**K151740 JAZZ System**Aug 27, 2015  
62 days to decisionK151740 · Product code: **OWI** · Orthopedic  
Source: <https://www.510kdatabase.net/k151740/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Fixation Cerclage, Sublaminar (OWI)
Date received	Jun 26, 2015
Decision date	Aug 27, 2015
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151740/> 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