

K191217 JAZZ PFAug 2, 2019
88 days to decisionK191217 · Product code: **OWI** · Orthopedic
Source: <https://www.510kdatabase.net/k191217/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Fixation Cerclage, Sublaminar (OWI)
Date received	May 6, 2019
Decision date	Aug 2, 2019
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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