FDA 510(k) Premarket Notification

K151740 JAZZ System

CLEARED

Aug 27, 2015
62 days to decision

K151740 · Product code: **OWI** · Orthopedic
Source: https://www.510kdatabase.net/k151740/

SUBMISSION DETAILS

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

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