FDA 510(k) Premarket Notification

K161058 Cannulated Screw

CLEARED

Jul 29, 2016
105 days to decision

K161058 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k161058/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Apr 15, 2016
Decision date	Jul 29, 2016
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Miami Device Solutions, LLC**
Location	Miami, FL, US
Contact	MARKKU BIEDERMANN
510(k) history	6 submissions · 6 cleared · 2016-2018