FDA 510(k) Premarket Notification

K132591 MAXLOCK EXTREME SYSTEM

CLEARED

Sep 17, 2013
29 days to decision

K132591 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k132591/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Aug 19, 2013
Decision date	Sep 17, 2013
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Orthohelix Surgical Designs, Inc.**
Location	Cleveland, OH, US
Contact	DEREK LEWIS
510(k) history	25 submissions · 25 cleared · 2005-2014