FDA 510(k) Premarket Notification

K130412 OSTEOMED EXTREMIFUSE SYSTEM

CLEARED

May 31, 2013
101 days to decision

K130412 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k130412/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Feb 19, 2013
Decision date	May 31, 2013
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Osteomed**
Location	Addison, TX, US
Contact	PIEDAD PENA
510(k) history	12 submissions · 12 cleared · 2012-2021