FDA 510(k) Premarket Notification

K141508 ROMEO 2 PAD POSTERIOR AXIAL DEVICE

CLEARED

Aug 21, 2014
76 days to decision

K141508 · Product code: **PEK** · Orthopedic
Source: https://www.510kdatabase.net/k141508/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinous Process Plate (PEK)
Date received	Jun 6, 2014
Decision date	Aug 21, 2014
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spineart**
Location	Geneva, CH
Contact	FRANCK PENNESI
510(k) history	44 submissions · 44 cleared · 2008-2023