FDA 510(k) Premarket Notification

K103111 FORZA SPACER SYSTEM

CLEARED

Mar 23, 2011
153 days to decision

K103111 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k103111/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Oct 21, 2010
Decision date	Mar 23, 2011
Days to decision	153 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Orthofix, Inc.**
Location	Mckinney, TX, US
Contact	DARLA CHEW
510(k) history	57 submissions · 57 cleared · 1996-2024