FDA 510(k) Premarket Notification

K142634 Biomet Spine Fusion System

CLEARED

Mar 12, 2015
176 days to decision

K142634 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k142634/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 17, 2014
Decision date	Mar 12, 2015
Days to decision	176 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biomet Spine, LLC**
Location	Broomfield, CO, US
Contact	Mike Medina
510(k) history	4 submissions · 4 cleared · 2014-2016