FDA 510(k) Premarket Notification

K151483 Biomet Spine Fusion System

CLEARED

Jul 31, 2015
59 days to decision

K151483 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k151483/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jun 2, 2015
Decision date	Jul 31, 2015
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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