FDA 510(k) Premarket Notification

K141791 BIOMET FUSION SYSTEM

CLEARED

Oct 9, 2014
99 days to decision

K141791 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k141791/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Jul 2, 2014
Decision date	Oct 9, 2014
Days to decision	99 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biomet Spine**
Location	Warsaw, IN, US
Contact	TED KUHN
510(k) history	19 submissions · 18 cleared · 2007-2016

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k141791/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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