FDA 510(k) Premarket Notification

K122989 BIOMET LATERAL SPACER SYSTEM

CLEARED

Oct 24, 2012
28 days to decision

K122989 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k122989/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 26, 2012
Decision date	Oct 24, 2012
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biomet Spine (Aka Ebi, LLC)**
Location	Parsippany, NJ, US
Contact	MARGARET F CROWE
510(k) history	13 submissions · 13 cleared · 2010-2014