FDA 510(k) Premarket Notification

K110650 ZYSTON ARC INTERBODY SPACER

CLEARED

Jun 30, 2011
118 days to decision

K110650 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k110650/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 4, 2011
Decision date	Jun 30, 2011
Days to decision	118 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