

K112014 ZYSTON STRAIGHT SPACER SYSTEMOct 17, 2011
95 days to decisionK112014 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k112014/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 14, 2011
Decision date	Oct 17, 2011
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomet Spine
Location	Warsaw, IN, US
Contact	JULIE A RYAN
510(k) history	19 submissions · 18 cleared · 2007-2016

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