FDA 510(k) Premarket Notification

CLEARED

K113561 TM ARDIS INTERBODY SYSTEM TM ARDIS INTERBODY SYSTEM INSTRUMENATION

May 29, 2012
180 days to decision

K113561 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k113561/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 1, 2011
Decision date	May 29, 2012
Days to decision	180 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Zimmer Trabecular Metal Technology**
Location	Parsippany, NJ, US
Contact	JUDITH ROSEN
510(k) history	11 submissions · 11 cleared · 2007-2014