FDA 510(k) Premarket Notification

K073202 ARDIS SPACER

CLEARED

Jan 30, 2008
78 days to decision

K073202 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k073202/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 13, 2007
Decision date	Jan 30, 2008
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Abbott Spine, Inc.**
Location	Austin, TX, US
Contact	MARITZA ELIAS
510(k) history	13 submissions · 13 cleared · 2005-2009