FDA 510(k) Premarket Notification

K112986 LATERAL FUSION DEVICE

CLEARED

May 1, 2012
208 days to decision

K112986 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k112986/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Oct 6, 2011
Decision date	May 1, 2012
Days to decision	208 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Integra Spine (Integra Lifesciences)**
Location	Medina, OH, US
Contact	DALE DAVISON
510(k) history	1 submissions · 1 cleared · 2012-2012