FDA 510(k) Premarket Notification

CLEARED

K100210 TRANS1 LATERAL INTERVERTEBRAL FUSION DEVICE, T

Aug 26, 2010
213 days to decision

K100210 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k100210/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jan 25, 2010
Decision date	Aug 26, 2010
Days to decision	213 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Trans1 Incorporated**
Location	Wilmington, NC, US
Contact	CHERYL WAGONER
510(k) history	9 submissions · 9 cleared · 2005-2012