FDA 510(k) Premarket Notification

K130506 IMSE P-TLIF

CLEARED

May 13, 2013
75 days to decision

K130506 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k130506/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Feb 27, 2013
Decision date	May 13, 2013
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Institute of Musculoskeletal Science & Education**
Location	Newtown Square, PA, US
Contact	JOHN MORAN
510(k) history	1 submissions · 1 cleared · 2013-2013