FDA 510(k) Premarket Notification

K153627 NuVasive® TLX Interbody System

CLEARED

Mar 17, 2016
90 days to decision

K153627 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k153627/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 18, 2015
Decision date	Mar 17, 2016
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nu Vasive, Incorporated**
Location	San Diego, CA, US
Contact	CYNTHIA ADAMS
510(k) history	112 submissions · 112 cleared · 2012-2023