

K153627 NuVasive® TLX Interbody SystemMar 17, 2016
90 days to decisionK153627 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153627/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026