FDA 510(k) Premarket Notification

CLEARED

K173025 NuVasive® MLX® – Medial Lateral Expandable Lumbar Interbody System

Feb 8, 2018
133 days to decision

K173025 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k173025/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 28, 2017
Decision date	Feb 8, 2018
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary
Other names	NuVasive® AP Expandable XLIF System

APPLICANT

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