FDA 510(k) Premarket Notification

K190418 NuVasive® VersaTie® System

CLEARED

Mar 21, 2019
28 days to decision

K190418 · Product code: **OWI** · Orthopedic
Source: https://www.510kdatabase.net/k190418/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Bone Fixation Cerclage, Sublaminar (OWI)
Date received	Feb 21, 2019
Decision date	Mar 21, 2019
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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