FDA 510(k) Premarket Notification

K221388 NuVasive Reline Cervical System

CLEARED

Sep 9, 2022
119 days to decision

K221388 · Product code: **NKG** · Orthopedic
Source: https://www.510kdatabase.net/k221388/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Posterior Cervical Screw System (NKG)
Date received	May 13, 2022
Decision date	Sep 9, 2022
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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