FDA 510(k) Premarket Notification

K221307 Edge Upper Cervical System

CLEARED

Jul 10, 2023
431 days to decision

K221307 · Product code: **NKG** · Orthopedic
Source: https://www.510kdatabase.net/k221307/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Posterior Cervical Screw System (NKG)
Date received	May 5, 2022
Decision date	Jul 10, 2023
Days to decision	431 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Spinal Simplicity, LLC**
Location	Philedelphia, PA, US
Contact	Adam Rogers
510(k) history	14 submissions · 14 cleared · 2015-2025