FDA 510(k) Premarket Notification

K172175 CapSure® PS System

CLEARED

Aug 16, 2017
28 days to decision

K172175 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k172175/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jul 19, 2017
Decision date	Aug 16, 2017
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spine Wave, Inc.**
Location	Shelton, CT, US
Contact	Amy Noccioli
510(k) history	57 submissions · 57 cleared · 2004-2025