FDA 510(k) Premarket Notification

K203506 PERLA® TL posterior osteosynthesis system

CLEARED

Jan 15, 2021
46 days to decision

K203506 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k203506/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Nov 30, 2020
Decision date	Jan 15, 2021
Days to decision	46 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Spineart**
Location	Geneva, CH
Contact	Franck Pennesi
510(k) history	44 submissions · 44 cleared · 2008-2023