FDA 510(k) Premarket Notification

K203222 PERLA TL Posterior Osteosynthesis System

CLEARED

Dec 17, 2020
45 days to decision

K203222 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k203222/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Nov 2, 2020
Decision date	Dec 17, 2020
Days to decision	45 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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