FDA 510(k) Premarket Notification

K190071 Perla® Posterior Cervico-Thoracic Fixation System

CLEARED

Feb 25, 2019
41 days to decision

K190071 · Product code: **NKG** · Orthopedic
Source: https://www.510kdatabase.net/k190071/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Posterior Cervical Screw System (NKG)
Date received	Jan 15, 2019
Decision date	Feb 25, 2019
Days to decision	41 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