FDA 510(k) Premarket Notification

K182339 LEUCADIA AUTOLOK™ Pedicle Screw System

CLEARED

Dec 12, 2018
106 days to decision

K182339 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k182339/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Aug 28, 2018
Decision date	Dec 12, 2018
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Clearview Orthopedic Development, LLC**
Location	Irvine, CA, US
Contact	Hartmut Loch
510(k) history	1 submissions · 1 cleared · 2018-2018