FDA 510(k) Premarket Notification

K182352 SP-LINK™ System

CLEARED

Nov 21, 2018
84 days to decision

K182352 · Product code: **PEK** · Orthopedic
Source: https://www.510kdatabase.net/k182352/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinous Process Plate (PEK)
Date received	Aug 29, 2018
Decision date	Nov 21, 2018
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medical Designs, LLC**
Location	Brandon, SD, US
Contact	Kristi Vondra
510(k) history	7 submissions · 7 cleared · 2000-2018