

K182352 SP-LINK™ SystemNov 21, 2018
84 days to decisionK182352 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182352/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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