FDA 510(k) Premarket Notification

K182542 The EPAD 2 System

CLEARED

Feb 22, 2019
158 days to decision

K182542 · Product code: **GWF** · Neurology
Source: https://www.510kdatabase.net/k182542/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Evoked Response (GWF)
Date received	Sep 17, 2018
Decision date	Feb 22, 2019
Days to decision	158 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Safeop Surgical, Inc.**
Location	Amherst, MA, US
Contact	Richard O'Brien
510(k) history	2 submissions · 2 cleared · 2014-2019

REGULATORY CONSULTANT

Consulting firm	**Alphatec Spine, Inc.**
Contact	Jeremy Markovich

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov