

**K182542 The EPAD 2 System**Feb 22, 2019  
158 days to decisionK182542 · Product code: **GWF** · Neurology  
Source: <https://www.510kdatabase.net/k182542/>**SUBMISSION DETAILS**

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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**

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Company	<b>Safeop Surgical, Inc.</b>
Location	Amherst, MA, US
Contact	Richard O'apos;Brien
510(k) history	2 submissions · 2 cleared · 2014-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Alphatec Spine, Inc.</b>
Contact	Jeremy Markovich

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

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