

**K171863 Anjon Bremer Halo System**Mar 19, 2018  
270 days to decisionK171863 · Product code: **JEC** · Orthopedic  
Source: <https://www.510kdatabase.net/k171863/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Component, Traction, Invasive (JEC)
Date received	Jun 22, 2017
Decision date	Mar 19, 2018
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Anjon Holdings, LLC</b>
Location	Jacksonville, FL, US
Contact	Tommy Mitchell
510(k) history	2 submissions · 2 cleared · 2018-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Kapstone Medical</b>
Contact	John Kapitan

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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