

**K161318 Phantom Fukushima Neurological Holding Systems,  
Phantom Mastability Neurological Holding Systems**

Mar 20, 2017  
313 days to decision

K161318 · Product code: **GZT** · Neurology  
Source: <https://www.510kdatabase.net/k161318/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Retractor, Self-retaining, For Neurosurgery (GZT)
Date received	May 11, 2016
Decision date	Mar 20, 2017
Days to decision	313 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Tedan Surgical Innovations, LLC</b>
Location	Sugar Land, TX, US
Contact	John Willis
510(k) history	2 submissions · 2 cleared · 2014-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k161318/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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