

**K190256 Rulo Radiofrequency Lesion Probe**Mar 8, 2019  
29 days to decisionK190256 · Product code: **GXI** · Neurology  
Source: <https://www.510kdatabase.net/k190256/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Probe, Radiofrequency Lesion (GXI)
Date received	Feb 7, 2019
Decision date	Mar 8, 2019
Days to decision	29 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Epimed International, Inc.</b>
Location	Johnstown, NY, US
Contact	Preston H. Frasier
510(k) history	14 submissions · 14 cleared · 1998-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Mark Job

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190256/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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