FDA 510(k) Premarket Notification

K190256 Rulo Radiofrequency Lesion Probe

CLEARED

Mar 8, 2019
29 days to decision

K190256 · Product code: **GXI** · Neurology
Source: https://www.510kdatabase.net/k190256/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Mark Job

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