

K232632 Racz Neurostat RF GeneratorMay 24, 2024
268 days to decisionK232632 · Product code: **GXD** · Neurology
Source: <https://www.510kdatabase.net/k232632/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, Lesion, Radiofrequency (GXD)
Date received	Aug 30, 2023
Decision date	May 24, 2024
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Epimed International
Location	Johnston, NY, US
Contact	Preston Frasier
510(k) history	2 submissions · 2 cleared · 2008-2024

REGULATORY CONSULTANT

Consulting firm	Medical Device Academy
Contact	Robert Packard

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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