FDA 510(k) Premarket Notification

K232632 Racz Neurostat RF Generator

CLEARED

May 24, 2024
268 days to decision

K232632 · 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