FDA 510(k) Premarket Notification

K220122 APEX 6

CLEARED

Mar 15, 2023
421 days to decision

K220122 · Product code: **GXD** · Neurology
Source: https://www.510kdatabase.net/k220122/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, Lesion, Radiofrequency (GXD)
Date received	Jan 18, 2022
Decision date	Mar 15, 2023
Days to decision	421 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Rf Innovations, Inc.**
Location	Middleton, MA, US
Contact	William Rittman
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Kamm & Associates**
Contact	Daniel Kamm

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