FDA 510(k) Premarket Notification

K231675 OneRF Ablation System

CLEARED

Dec 6, 2023
181 days to decision

K231675 · Product code: **GXD** · Neurology
Source: https://www.510kdatabase.net/k231675/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, Lesion, Radiofrequency (GXD)
Date received	Jun 8, 2023
Decision date	Dec 6, 2023
Days to decision	181 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Neuroone Medical Technologies Corp.**
Location	Eden Prairie, MN, US
Contact	Debra Kridner
510(k) history	4 submissions · 4 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	John Doucet

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