

**K242841 Disposable RF Electrode
(RFDE-5/RFDE-10/RFDE-15/RFDE-20)**May 27, 2025
250 days to decisionK242841 · Product code: **GXI** · Neurology
Source: <https://www.510kdatabase.net/k242841/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Probe, Radiofrequency Lesion (GXI)
Date received	Sep 19, 2024
Decision date	May 27, 2025
Days to decision	250 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Medical
Location	S,Mta Clara, CA, US
Contact	Elijah Canal
Website	https://www.abbott.com
510(k) history	57 submissions · 57 cleared · 2019-2026

Abbott Medical is a global healthcare technology company headquartered in Santa Clara, US. The company specializes in life-changing medical devices and diagnostic solutions across multiple therapeutic areas. Abbott Medical maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions. The company's primary focus is Cardiovascular devices, which represent 94% of its submission portfolio. Clearances span from 2019 to 2026, with recent activity demonstrating continued innovation in interventional cardiology and electrophysiology systems. R...