FDA 510(k) Premarket Notification

K212666 Neuromark System

CLEARED

Oct 22, 2021
60 days to decision

K212666 · Product code: **GEI** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k212666/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Aug 23, 2021
Decision date	Oct 22, 2021
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Neurent Medical**
Location	Galway, IE
Contact	Kenny Walsh
510(k) history	2 submissions · 2 cleared · 2021-2022