FDA 510(k) Premarket Notification

CLEARED

K190703 Neuro-IOM system with Neuro-IOM.NET software

May 22, 2021
796 days to decision

K190703 · Product code: **GWF** · Neurology
Source: https://www.510kdatabase.net/k190703/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Evoked Response (GWF)
Date received	Mar 18, 2019
Decision date	May 22, 2021
Days to decision	796 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Neurosoft , Ltd.**
Location	Abano Terme, Padova, IT
Contact	Eugene Polezhaev
510(k) history	3 submissions · 3 cleared · 2015-2022

REGULATORY CONSULTANT

Consulting firm	**Makromed, Inc.**
Contact	Barry V Ashar

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