FDA 510(k) Premarket Notification

K202913 NeuroCap (Model DEC22)

CLEARED

Mar 5, 2021
157 days to decision

K202913 · Product code: **GXY** · Neurology
Source: https://www.510kdatabase.net/k202913/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Sep 29, 2020
Decision date	Mar 5, 2021
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Memory MD, Inc.**
Location	New York, NY, US
Contact	Boris Goldstein
510(k) history	3 submissions · 3 cleared · 2018-2021

REGULATORY CONSULTANT

Consulting firm	**Mtak, LLC**
Contact	Mike Corcoran

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