FDA 510(k) Premarket Notification

K240668 Amydi-med Disposable Non-invasive EEG electrodes

CLEARED

Mar 19, 2024
11 days to decision

K240668 · Product code: **GXY** · Neurology
Source: https://www.510kdatabase.net/k240668/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Mar 8, 2024
Decision date	Mar 19, 2024
Days to decision	11 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Amydi-Med Electrics Tech Co., Ltd.**
Location	Shenzhen, CN
Contact	Cuifang Yuan
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	Dave Yungvirt

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