FDA 510(k) Premarket Notification

K223775 EZ-STIK Electrodes

CLEARED

Jan 3, 2023
18 days to decision

K223775 · Product code: **GXY** · Neurology
Source: https://www.510kdatabase.net/k223775/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Dec 16, 2022
Decision date	Jan 3, 2023
Days to decision	18 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**South Dakota Partners**
Location	Clear Lake, SD, US
Contact	Mike Plunkett
510(k) history	1 submissions · 1 cleared · 2023-2023

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