FDA 510(k) Premarket Notification

K241160 CAIs Sensor (CAIs-001)

CLEARED

Dec 13, 2024
231 days to decision

K241160 · Product code: **GXY** · Neurology
Source: https://www.510kdatabase.net/k241160/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Apr 26, 2024
Decision date	Dec 13, 2024
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Brainu Co., Ltd.**
Location	Seongnam-Si, KR
Contact	Sangwoo Choi
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**CTI Co., Ltd.**
Contact	Yeonwoo Lee

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