

K212191 Adhesive ElectrodesOct 6, 2021
86 days to decisionK212191 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k212191/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Jul 12, 2021
Decision date	Oct 6, 2021
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Voncare Medical Device Co., Ltd.
Location	Boluo County, Huizhou, CN
Contact	Jimmy Zhai
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Irc
Contact	Charles Mack

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

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