

K182111 DL Self-adhesive ElectrodeJan 17, 2019
164 days to decisionK182111 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k182111/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Aug 6, 2018
Decision date	Jan 17, 2019
Days to decision	164 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shaoxing DL Healthcare Co., Ltd.
Location	Shaoxing, CN
Contact	Zhao Qingya
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Shanghai CV Technology Co., Ltd.
Contact	Doris Dong

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

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