

K213884 Disposable EEG cableMay 6, 2022
144 days to decisionK213884 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k213884/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Electrode, Cutaneous (GXY)
Date received	Dec 13, 2021
Decision date	May 6, 2022
Days to decision	144 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Changke Connect Electronics Co., Ltd.
Location	Longgang District, Shenzhen, CN
Contact	Yahui Zhou
510(k) history	8 submissions · 8 cleared · 2019-2022

REGULATORY CONSULTANT

Consulting firm	Chonconn Medical Device Consulting Co., Ltd.
Contact	Kevin Wang

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

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