

K221199 Conductive Silicone Electrode (model: Foot Pad Electrode, Cupping Electrode, Point Electrode)Dec 19, 2023
602 days to decisionK221199 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k221199/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Apr 26, 2022
Decision date	Dec 19, 2023
Days to decision	602 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Green Island International Tcm Group Limited
Location	Hongkong, CN
Contact	Zhang Shuai
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Guangzhou GLOMED Biological Technology Co., Ltd.
Contact	Cassie Lee

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

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