

K200942 Well-Life Garment Electrodes (GM Series)Jun 1, 2021
419 days to decisionK200942 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k200942/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Apr 8, 2020
Decision date	Jun 1, 2021
Days to decision	419 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Well-Life Healthcare Limited
Location	Kowloon, HK
Contact	Jenny Hsieh
510(k) history	22 submissions · 22 cleared · 2006-2024

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