

K220002 Dexus Prosthetics System (Model: MSL1, MSR1)Sep 9, 2022
248 days to decisionK220002 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k220002/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Jan 4, 2022
Decision date	Sep 9, 2022
Days to decision	248 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zhejiang Qiangnao Technology Co.,Ltd
Location	Hangzhou, CN
Contact	Boyuan Meng
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Share Info (Guangzhou) Medical Consultant , 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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