

K213925 MyoCycle MC-2 (Home / Home + / Pro / Pro +)Apr 25, 2022
130 days to decisionK213925 · Product code: **GZI** · Neurology
Source: <https://www.510kdatabase.net/k213925/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Neuromuscular, External Functional (GZI)
Date received	Dec 16, 2021
Decision date	Apr 25, 2022
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Myolyn, LLC
Location	Gainesville, FL, US
Contact	Matthew Bellman
510(k) history	2 submissions · 2 cleared · 2017-2022

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