

K231569 ManaFlexx 2 (model: MF002-RX, MF002-OTC)Nov 3, 2023
156 days to decisionK231569 · Product code: **NUH** · Neurology
Source: <https://www.510kdatabase.net/k231569/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	May 31, 2023
Decision date	Nov 3, 2023
Days to decision	156 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Manamed, Inc.
Location	Costa Mesa, CA, US
Contact	Trevor Theriot
510(k) history	7 submissions · 7 cleared · 2016-2023

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