FDA 510(k) Premarket Notification

K241365 Pixie Pulse (SM9068)

CLEARED

Aug 12, 2024
90 days to decision

K241365 · Product code: **NUH** · Neurology
Source: https://www.510kdatabase.net/k241365/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	May 14, 2024
Decision date	Aug 12, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Pixie Cup, LLC**
Location	Walnut Shade, MO, US
Contact	Amber English
510(k) history	1 submissions · 1 cleared · 2024-2024