FDA 510(k) Premarket Notification

K233092 Pain Therapy Device (SM9075, SM9910, SM9067, SM9587W)

CLEARED

Feb 12, 2024
139 days to decision

K233092 · Product code: **NUH** · Neurology
Source: https://www.510kdatabase.net/k233092/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Sep 26, 2023
Decision date	Feb 12, 2024
Days to decision	139 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Chongqing Rob Linka Science and Technology Co., Ltd.**
Location	Chongqing, CN
Contact	Huirong Lu
510(k) history	4 submissions · 4 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	**Guangzhou Glomed Biological Technoloy Co., Ltd.**
Contact	Cassie Lee

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov