FDA 510(k) Premarket Notification

CLEARED

K212989 Low-frequency Stimulator (Model: AST-645, AST-646)

Nov 22, 2021
63 days to decision

K212989 · Product code: **NUH** · Neurology
Source: https://www.510kdatabase.net/k212989/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Sep 20, 2021
Decision date	Nov 22, 2021
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Osto Technology Co., Ltd.**
Location	Shenzhen, CN
Contact	Li Yang
510(k) history	5 submissions · 5 cleared · 2018-2021

REGULATORY CONSULTANT

Consulting firm	**Guangzhou GLOMED Biological Technology Co., Ltd.**
Contact	Cassie Lee

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