

K223047 NeuroSwift ProJun 29, 2023
273 days to decisionK223047 · Product code: **GWN** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k223047/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nystagmograph (GWN)
Date received	Sep 29, 2022
Decision date	Jun 29, 2023
Days to decision	273 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neurobit Technologies Co., Ltd.
Location	Taipei, TW
Contact	Chun-Chen Yang
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Intellrac Consulting , Ltd.
Contact	Tyra Chiu

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

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