

K200705 Nurochek SystemApr 23, 2020
36 days to decisionK200705 · Product code: **GWE** · Neurology
Source: <https://www.510kdatabase.net/k200705/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Photic, Evoked Response (GWE)
Date received	Mar 18, 2020
Decision date	Apr 23, 2020
Days to decision	36 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cryptych Pty, Ltd.
Location	North Sydney, AU
Contact	Angela Roche
510(k) history	2 submissions · 2 cleared · 2016-2020

REGULATORY CONSULTANT

Consulting firm	Accelerated Device Approval Services
Contact	Rafael Aguila

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200705/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 19, 2026