FDA 510(k) Premarket Notification

K200705 Nurochek System

CLEARED

Apr 23, 2020
36 days to decision

K200705 · 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