FDA 510(k) Premarket Notification

K221471 E3 and Profile

CLEARED

Nov 22, 2022
186 days to decision

K221471 · Product code: **GWE** · Ophthalmic
Source: https://www.510kdatabase.net/k221471/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Photic, Evoked Response (GWE)
Date received	May 20, 2022
Decision date	Nov 22, 2022
Days to decision	186 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Diagnosys, LLC**
Location	Lowell, MA, US
Contact	Jeffrey Farmer
510(k) history	1 submissions · 1 cleared · 2022-2022