

K221471 E3 and ProfileNov 22, 2022
186 days to decisionK221471 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221471/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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