

K191700 EyeStatDec 9, 2019
167 days to decisionK191700 · Product code: **GZP** · Neurology
Source: <https://www.510kdatabase.net/k191700/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Mechanical, Evoked Response (GZP)
Date received	Jun 25, 2019
Decision date	Dec 9, 2019
Days to decision	167 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Blinktbi, Inc.
Location	Charleston, SC, US
Contact	Ryan Fiorini
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	S Mathur
Contact	S. Mathur

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191700/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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