FDA 510(k) Premarket Notification

K191700 EyeStat

CLEARED

Dec 9, 2019
167 days to decision

K191700 · 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