FDA 510(k) Premarket Notification

K202927 EYE-SYNC

CLEARED

Oct 2, 2021
368 days to decision

K202927 · Product code: **QEA** · Neurology
Source: https://www.510kdatabase.net/k202927/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Brain Injury Adjunctive Interpretive Oculomotor Assessment Aid (QEA)
Date received	Sep 29, 2020
Decision date	Oct 2, 2021
Days to decision	368 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Syncthink, Inc.**
Location	Boston, MA, US
Contact	Dan Beeler
510(k) history	2 submissions · 2 cleared · 2016-2021

REGULATORY CONSULTANT

Consulting firm	**Arina Consulting, LLC**
Contact	Allison Kumar

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