FDA 510(k) Premarket Notification

K232930 VERVE

CLEARED

Jun 13, 2024
267 days to decision

K232930 · Product code: **SBN** · Ophthalmic
Source: https://www.510kdatabase.net/k232930/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Digital Therapy Device For Convergence Insufficiency (SBN)
Date received	Sep 20, 2023
Decision date	Jun 13, 2024
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Oculomotor Technologies**
Location	Princeton, NJ, US
Contact	Chang Yaramothu, Ph.D.
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**RQM+**
Contact	Allison Komiyama, Ph.D., RAC

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