

K181771 RightEye Vision SystemSep 28, 2018
87 days to decisionK181771 · Product code: **GWN** · Ophthalmic
Source: <https://www.510kdatabase.net/k181771/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nystagmograph (GWN)
Date received	Jul 3, 2018
Decision date	Sep 28, 2018
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Righteye, LLC
Location	Bethesda, MD, US
Contact	Adam Gross
510(k) history	1 submissions · 1 cleared · 2018-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181771/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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