

K203082 Insight Infrared Video GogglesNov 12, 2020
30 days to decisionK203082 · Product code: **GWN** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k203082/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nystagmograph (GWN)
Date received	Oct 13, 2020
Decision date	Nov 12, 2020
Days to decision	30 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vestibular First
Location	Broomall, PA, US
Contact	Helena Esmonde
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	Dave Yungvirt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203082/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 15, 2026