

**K200534 VisualEyes**Aug 12, 2020  
163 days to decisionK200534 · Product code: **GWN** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k200534/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nystagmograph (GWN)
Date received	Mar 2, 2020
Decision date	Aug 12, 2020
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Interacoustics A/S</b>
Location	Minnesota, MN, US
Contact	Erik Nielson
510(k) history	17 submissions · 17 cleared · 2006-2020

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200534/> 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