

# K192186 I-Portal Neuro Otologic Test Center, I-Portal Video Nystagmography System, I-Portal Portable Assessment System - Nysragmograph

Nov 29, 2019  
109 days to decision

K192186 · Product code: **GWN** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k192186/>

## SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nystagmograph (GWN)
Date received	Aug 12, 2019
Decision date	Nov 29, 2019
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

## APPLICANT

Company	<b>Neurologn USA, LLC</b>
Location	Pittsburgh, PA, US
Contact	Aura Kullmann
510(k) history	1 submissions · 1 cleared · 2019-2019

## CLINICAL EVIDENCE - NCT01832714

### Assessment of Oculomotor, Vestibular and Reaction Time Response Following a Concussive Event

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	300 patients (actual)
Study sites	2 sites
Condition studied	Concussion, Mild; Concussion, Intermediate; Concussion, Severe
Study type	Observational
Completion date	Nov 1, 2015
Sponsor	Neurologn (Industry)

## Primary outcome

Variability of latency in reflexive saccades (ms)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT01832714](https://clinicaltrials.gov/study/NCT01832714)

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k192186/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)), ClinicalTrials.gov (U.S. National Library of Medicine). 510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated June 30, 2026