FDA 510(k) Premarket Notification

CLEARED

K260566 SMARTVERTIGO™ Vestibular Assessment System

Jul 30, 2026
161 days to decision

K260566 · Product code: **GWN** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k260566/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nystagmograph (GWN)
Date received	Feb 19, 2026
Decision date	Jul 30, 2026
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**VertigoDx, Inc.**
Location	Wilmington, DE, US
Contact	Trevor Meyerowitz
510(k) history	1 submissions · 1 cleared · 2026-2026