

**Coral Gables Vestibular Clinic**

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FDA CLEARED · K260566**CLASS II****VISIT SUMMARY****RESEARCH / FDA CASE SUMMARY**Visit **06 Sept 2026 · 07:23**Report no. **VDX-2026-00004**

Template: Research / FDA case summary

PATIENT**Margaret Ellison**DOB **14 Mar 1961**File no. **CGV-04471**Sex **F**Referred by **Alan Reyes, MD (primary care)****CLINICIAN****Sarah Whitfield, PT, DPT**Profession **Physical Therapist (PT, DPT)**Device **SmartVertigo · iPhone 14 Pro Max**Reg. no. **FL PT 30412**Classifier **V4 (v24)****IDENTIFIERS**

Case VDX-CHK32854 · date of service 01 Jul 2026.

CLASSIFIER VERSUS CLINICIAN

Sitting — eye tested: right; down-beating; peak SPV 13.7°/s (moderate); latency 0 s; duration 7 s; classifier confidence 38%; on-device label: tested and clear; second-opinion head verdict: not documented; clinician verdict: —; agreement: no.

Note: Clinician on sitting after treatment — "a quick check of the eyes, and that is clear".

Lying — eye tested: left; down-beating; peak SPV 3.3°/s (weak); latency 0 s; duration 9 s; classifier confidence 67%; on-device label: tested and clear (Supine); second-opinion head verdict: not documented; clinician verdict: —; agreement: no.

Note: Clinician — "Nothing much there."

Roll Left — eye tested: left; right-beating horizontal; peak SPV 5.1°/s (weak); latency 0 s; duration 2 s; classifier confidence 67%; on-device label: tested and clear; second-opinion head verdict: not documented; clinician verdict: —; agreement: no.

Note: Patient — "That is fine. Nothing."

Roll Right — eye tested: right; left-beating horizontal; peak SPV 4.2°/s (weak); latency 0 s; duration 16 s; classifier confidence 92%; on-device label: Ageo HN, duration <60 s, symptoms dizziness; second-opinion head verdict: not documented; clinician verdict: —; agreement: no.

Note: Symptoms reproduced — Patient: "Oh. Oh, that is it. That is the spinning." Clinician: "I can see the eyes beating from side to side, and it is settling already."

Dix-Hallpike Left — eye tested: left; down-beating; peak SPV 20.4°/s (strong); latency 0 s; duration 5 s; classifier confidence 71%; on-device label: DBN, duration <60 s; second-opinion head verdict: not documented; clinician verdict: —; agreement: no.

Note: Clinician — "I can see a small down-beating nystagmus on the left, but you are not spinning much."

Dix-Hallpike Right — eye tested: right; down-beating; peak SPV 26.5°/s (strong); latency 1 s; duration 12 s; classifier confidence 76%; on-device label: DBN, duration <60 s, latency 16-30 s, symptoms dizziness; second-opinion head verdict: not documented; clinician verdict: —; agreement: no.

Note: Delayed onset with torsion and symptoms reproduced — Clinician: "That is a strong down-beating nystagmus, and I can see the eye rolling as well." Patient: "The room is going over." On re-check after treatment: "No nystagmus", and the patient denied spinning.

Straight Head Hang — eye tested: right; up-torsional, counter-clockwise; peak SPV 12.6°/s (moderate); latency 1 s; duration 14 s; classifier confidence 81%; on-device label: UTN CC, duration <60 s, latency 2-15 s, symptoms dizziness; second-opinion head verdict: not documented; clinician verdict: —; agreement: no.

Note: Clinician — "There is an up-beating and twisting nystagmus there, counter-clockwise. That fits with the front canal on the right as well."

DEVICE AND MODEL

Classifier SmartVertigo V4; app build not documented; on-device contract version not documented; capture fps not documented.

OUTCOME

R Yacovino manoeuvre and R Epley manoeuvre performed for otoliths in the right anterior and right posterior canals; immediate post-treatment right Dix-Hallpike showed no nystagmus and no symptoms (resolved at same visit); review arranged in one week, follow-up result not documented.

CODING

ICD-10 H81.11 (right) benign paroxysmal vertigo; CPT 95992 canalith repositioning procedure (from the recorded treatment)

DATA NOTES

Data note: handset recorded Right Roll as Ageo HN vs classifier L HN (left-beating horizontal).
Data note: handset recorded right Dix-Hallpike latency 16-30 s vs classifier latency 1 s.
Data note: handset recorded Sitting, Supine and Left Roll as tested and clear, while the classifier returned DBN, DBN and R HN respectively at low peak SPV.
Data note: transcript date of recording 06 Sep 2026 differs from the handset date of service 01 Jul 2026.

Sarah Whitfield, PT, DPT
Physical Therapist (PT, DPT) · Coral Gables Vestibular Clinic
Signed electronically · 06 Sept 2026 · 07:23

SmartVertigo classifier V4 (v24) · FDA cleared K260566 · Drafted by VertigoDx Scribe from the clinician's dictation and the SmartVertigo examination; reviewed and approved by the signing clinician. Generated 08 Sept 2026 · 04:14.