November 29, 2019

Neuro Kinetics, Inc.
Aura Kullmann
Clinical Trial Manager
128 Gamma Drive
Pittsburgh, Pennsylvania 15238

Re: K192186
Trade/Device Name: I-Norm 100_18-45
Regulation Number: 21 CFR 882.1460
Regulation Name: Nystagmograph
Regulatory Class: Class II
Product Code: GWN
Dated: October 24, 2019
Received: October 31, 2019

Dear Aura Kullmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Ryan
Division Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192186

Device Name

I-Norm 100_18-45

Indications for Use *(Describe)*

I-Norm 100_18-45 is a quantitative tool for the comparison of patient measurements to a database of known normal subjects ages 18-45. I-Norm 100_18-45 presents data for interpretation by qualified medical personnel trained in vestibular, neurologic, neurotologic, and neuro-ophtalmic diagnostic testing. I-Norm 100_18-45 is applicable to individuals only in the 18-45 age range.

The proposed intended use for I-Norm 100_18-45 is as following:

I-Norm 100_18-45 is designed to be used with the family of I-Portal® devices:

- I-Portal® Neuro Otologic Test Center (NOTC) (cleared by K083603, K143607)
- I-Portal® Video-Nystagmography System (VNG) – SVNG-2 (cleared by K143607)
- I-Portal® Portable Assessment System™ Nystagmograph (I-PAS™) (cleared by K171884)

The I-Portal® devices with I-Norm 100_18-45 are nystagmograph devices intended for use in vestibular and neurotologic diagnostic testing. The addition of the I-Norm 100_18-45 does not change the intended use or the indication for use for these devices from their original clearances listed above.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

I. Submitter

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Date Prepared: October 24, 2019

II. Device

Trade Name	Proprietary Name
• I-Portal® Neuro Otologic Test Center (NOTC) with I-Norm 100_18-45	• I-Portal® Neuro Otologic Test Center (NOTC) with I-Norm 100_18-45
• I-Portal® Video Nystagmography System (VNG) with I-Norm 100_18-45	• I-Portal® Super VNG System 2 (SVNG-2) with I-Norm 100_18-45
• I-Portal® Portable Assessment System Nystagmograph (I-PAS™) with I-Norm 100_18-45	• I-Portal® Portable Assessment System Nystagmograph (I-PAS™) with I-Norm 100_18-45

Common/Usual Name: Nystagmograph
Classification Name: Nystagmograph
Product Classification: Class II, § 882.1460, Product Code GWN

III. Predicate Device

Predicate Devices cleared by K083603, K143607, K171884 with VEST™ software (K181025)

- I-Portal® Neuro Otologic Test Center (NOTC) (K083603, K143607)
- I-Portal® Video Nystagmography System (VNG) (K143607)
- I-Portal® Portable Assessment System Nystagmograph (I-PAS™) (K171884)

IV. Device Description

I-Norm 100_18-45 is a software package that contains normative data for the segment of population ages 18 to 45, for oculomotor, vestibular, reaction time and cognitive (OVRT-C) tests delivered on the family of I-Portal® devices described below.

All I-Portal® devices function as nystagmographs, defined by 21 CFR 882.1460 as "devices used to measure, record, or visually display the involuntary movements (nystagmus) of the eyeball." Through their nystagmograph functionality, the I-Portal® devices are indicated for use as a measurement tool to assist trained physicians in their analysis of vestibular and neurotologic disorders, requiring a separation of central and peripheral nervous system deficits. The I-Portal® devices are used in an institutional environment on the order of a physician.

The I-Portal® NOTC features a rotational chair, optokinetic (OKN) optical stimulus, Pursuit Tracker (PT) laser target generator, I-Portal Video Oculography (VOG), I-Portal® and VEST™ software, and a test enclosure equipped with a communication system. Through the use of these elements and the VEST™ analysis software, the physician is able to schedule a set of tests designed to help isolate, identify and understand oculomotor, neurologic and vestibular functions and related possible disorders.

The I-Portal® VNG offers a subset of the NOTC tests and additional vestibular tests through a device with a smaller physical footprint. The VNG has many of the same elements used in the NOTC configuration: OKN optical stimulus, PT laser target generator, VOG, I-Portal and VEST™ software platforms. However, unlike the NOTC, it does not have either the rotational chair or the enclosure & communication system, but the VNG can collect and analyze data from caloric and position tests. The VNG configuration is typically used in smaller clinics or conditions requiring a smaller sized device or some mobility.

The I-PAS™ is a portable, compact, 3D, head-mounted display system with integrated eye tracking that offers a set of tests equivalent to the VNG and additional vestibular and oculomotor tests, but with a smaller physical footprint. Stimuli are presented on a high-resolution digital screen (2560 x 1440 pixels) mounted in a virtual reality-like goggle system. The nature of the integrated display monitor in I-PAS™ obstructs the patients' view of the external environment and ambient light.

Software: All I-Portal® devices use *VEST™ software* to deliver a battery of oculomotor, vestibular, reaction time and cognitive (OVRT-C) tests and *I-Portal® software* to record eye movements and reaction time responses during these tests. The analysis of OVRT-C tests performed by VEST™ software provides the clinician with a number of physiological measurements to aid in the assessment of vestibular and neurotologic disorders. **This application seeks to add I-Norm 100_18-45, a normative oculomotor, vestibular, reaction time and cognitive test database for ages 18-45 to the VEST™ software.** The normative database will be a quantitative tool for the comparison of patient measurements to a database of known 18-45 year old subjects without oculomotor and vestibular disorders (clinical data that support this application are presented in detail in the normative data user manual). This comparison will enable physicians to evaluate possible abnormalities by identifying values outside of normal ranges, and therefore used by physicians in their diagnosis of vestibular disorders.

V. Intended Use / Indications for Use

The indication for use for I-Norm 100_18-45 is as following:

"I-Norm 100_18-45 is a quantitative tool for the comparison of patient measurements to a database of known normal subjects ages 18-45. I-Norm 100_18-45 presents data for interpretation by qualified medical personnel trained in vestibular, neurologic, neurotologic, and neuro-ophthalmic diagnostic testing. I-Norm 100_18-45 is applicable to individuals only in the 18-45 age range."

The intended use for I-Norm 100_18-45 is as following:

I-Norm 100_18-45 is designed to be used with the family of I-Portal® devices:

- I-Portal® Neuro Otologic Test Center (NOTC) (cleared by K083603, K143607)
- I-Portal® Video-Nystagmography System (VNG) – SVNG-2 (cleared by K143607)
- I-Portal® Portable Assessment System™ Nystagmograph (I-PAS™) (cleared by K171884)

The I-Portal® devices with I-Norm 100_18-45 are nystagmograph devices intended for use in vestibular and neurotologic diagnostic testing. The addition of the I-Norm 100_18-45 does not change the intended use or the indication for use for these devices from their original clearances listed above.

VI. Technological Characteristics

The modified I-Portal® devices with the addition of VEST™ with I-Norm 100_18-45 have the same technological characteristics as their predicate devices, as cleared by K083603, K143607 and K171884.

I-Portal® devices provide visual and auditory stimuli while recording the horizontal, vertical, torsional, and pupil changes of a subject's eyes. NOTC provides additional motion stimuli. The subject's motor reaction times are recorded via a small, wired, hand-held trigger button box. Two high speed digital infrared cameras (940nm; sampling rate 100 to 500 frames/sec) transmit video images to a computer via a USB3 communication protocol. Spatial resolution for horizontal and vertical eye tracking and torsion is <0.01 degrees; eye tracking range is ±30 degrees horizontal, ±20 degrees vertical and ±10 degrees torsional. NKI's patented synchronization methods align outputs of left and right eyes with the stimulus presentation. I-Portal® software captures, time stamps, and analyzes the digital images of the eye, collecting horizontal, vertical, torsional, and pupil data. Each eye is tracked separately to enable measuring conjugacy and performance differences between eyes.

VEST™ software operates the hardware, manages and captures the stimulus profiles, integrates I-Portal® eye-tracking data, and analyzes data generating a comprehensive set of over 500 clinically relevant metrics. The addition of the I-Norm 100_18-45 to the VEST™ software does not change the technological performance of any I-Portal® devices.

I-Norm 100_18-45 provides the clinicians a choice of visualizing patient's data (when patient is 18-45 years old) in the context of a known normative database.

VII. Performance Data: Non-Clinical and Clinical Performance Data

a) Clinical Performance Data

Clinical data are provided to support the intended use for the I-Portal® devices with I-Norm 100_18-45 and to demonstrate substantial equivalence to the predicate devices. A detailed description of data collection and analysis is included in the normative data user manual. Below is a summary of clinical testing.

1. Subject Selection Criteria

Data were collected from a total of 466 males and females ages 18-45 of all races that met the inclusion/exclusion criteria approved by IRB protocols. Subjects were recruited at 3 different sites: the University of Miami, Naval Medical Center San Diego and Madigan Army Medical Center. Subjects were recruited from the intended population of use, which included non-professional athletes who participate in intercollegiate athletics, civilians and military service members. This mixture ensures appropriate representation of different levels of activity and skills encountered in the general population. Exclusion criteria were focused on conditions/diseases that could impact the oculomotor and vestibular tests. These include a history of brain injury, repeated blast exposure, presence of severe aphasia, history of diagnosed neuropsychiatric disorders, e.g., hypochondriasis, major depression, schizophrenia, neurodegenerative disorders, disorders of hearing and balance, e.g., Meniere's disease, multiple sclerosis, vestibular neuritis, vestibular schwannoma, sudden sensorineural hearing loss, cerebrovascular disorders, history of ear operation other than myringotomy tube in the past, and systemic disorders, e.g., chronic renal failure, cirrhosis of the liver. Pregnancy was also excluded. The complete details for subject recruitment, sites, IRB approvals and inclusion/exclusion criteria are included in the user manual.

2. Oculomotor, vestibular, reaction time and cognitive tests

The participants were tested with a battery of oculomotor, vestibular, reaction time and cognitive (OVRT-C) tests, on either the NOTC (300 subjects) or I-PAS™ (166 subjects) devices (Table 5-1). The devices are substantially equivalent as described in the K083603, K143607 and K171884, use the same I-Portal® eye tracking software and VEST™ analysis software. Thus, the data obtained from the two devices were pooled. The tests and variable analyzed are used in clinical practice for evaluation of vestibular and neuro otologic function.

	Table 5-1. Oculomotor, vestibular, reaction time and cognitive (OVRT-C) tests	**I-Portal® NOTC**	**I-PAS™**
1	Saccade - Random, Horizontal	X	X
2	Saccade - Random, Vertical	X	X
3	Smooth Pursuit - Horizontal 0.1Hz, 0.75Hz	X	X
4	Smooth Pursuit - Vertical 0.1Hz, 0.75Hz	X	X
5	Optokinetic (OKN) 20deg/s, 60deg/s	X	X
6	Subjective Visual Vertical	X	X
7	Subjective Visual Horizontal	X	X
8	Sinusoidal Harmonic Acceleration (SHA; 0.02Hz, 0.64Hz) (Chair rotation sinusoidal)	X	
9	Visual Enhancement 0.64Hz	X	

10	Visual Suppression and Interaction 0.64Hz	X	
11	controlled rotation Head Impulse Test (crHIT)	X	
12	Visual Reaction Time		X
13	Auditory Reaction Time	X	X
14	Saccade and Reaction Time	X	X
15	Predictive Saccades	X	X
16	Antisaccades	X	X

Results

Data were analyzed using a univariate general linear model for the effect of age, gender and combined age x gender on variables describing OVRT-C tests (Table 5-2). When statistical significance was demonstrated differences were evaluated and when deemed appropriate data were partitioned by groups. Using non-parametric methods, the 95% (2.5^{th} and 97.5^{th}) reference interval (RI) with 90% confidence interval (CI) on lower and upper limits was calculated. For one sided variables either the 2.5^{th} or 97.5^{th} percentile is presented. In addition, the 2.5^{th}, 5^{th}, 10^{th}, 25^{th}, 75^{th}, 90^{th}, 95^{th} and 97.5^{th} percentiles are provided in the user manual for a completely informed understanding of where subject data fall within the general population.

In summary, these results (Table 5-2) constitute a normative oculomotor and vestibular database for the tests listed in this application for ages 18-45.

User display for I-Norm 100 18-45

1. Software: VEST™ software, as cleared by K181025, contains the coding necessary to incorporate the I-Norm 100_18-45. Addition of this database does not in any way alter the raw data or analysis results gathered from the patient. VEST™ software will display the normative data in two forms to allow clinicians to quickly determine which values and how many of these values are within or outside the norms:
   a) *Graphical presentation.* In the graphs generated after data acquisition, the upper and lower boundaries of the RI will be indicated by gray shaded areas. Test variables that are outside the norms will fall in these shaded areas. Test variables within the norms will fall in between the shaded areas. This feature allows clinicians to quickly visualize which test variables are out of norms.
   b) Numerical presentation.
      a. For many variables, the percentage or test values that fall "Within Norm" will be presented. This feature allows clinicians to quickly visualize how many of the variables within a test are out of norms.
      b. There are variables for which VEST™ provides a numerical value but the screen does not has an indication of "Within Norm". The norms for these variables are included in the user manual.
2. User Manual: The normative database manual contains all norms presented in table format. A summary of all norms found in the manual is presented in Table 5-2 below.

	Table 5-2. Normative data for OVRT-C tests: 95% RI with 90% CI				
Test	**Variable**	**RI lower limit**	**RI upper limit**	**90% CI for lower limit RI**	**90% CI for upper limit RI**
1. Saccade – Random, Horizontal	Latency (sec)	n/a	0.22	n/a	0.21 - 0.22
	Accuracy (%)	81	103	80 - 82	101 - 105
	Final accuracy (%)	89	104	87 - 89	102 - 106
	AUF (deg^2/sec)	8239	n/a	7706 - 8351	n/a
	Peak Velocity (deg/sec) for eye displacement of: 30 (deg) 25 (deg) 20 (deg) 15 (deg) 10 (deg) 5 (deg)	 356 322 301 272 241 121	 n/a n/a n/a n/a n/a n/a	 355 – 374 314 – 332 292 – 303 265 – 278 235 – 242 117 – 124	 n/a n/a n/a n/a n/a n/a
2. Saccade – Random, Vertical	Latency (sec)	n/a	0.23	n/a	0.22 - 0.23
	Accuracy (%)	75	109	73 - 76	108 - 112
	Final accuracy (%)	79	107	78 - 80	106 - 110
	AUF (deg^2/sec)	7630	n/a	6937- 7855	n/a
	Peak Velocity (deg/sec) for eye displacement of: 30 (deg) 25 (deg) 20 (deg) 15 (deg) 10 (deg) 5 (deg)	 337 287 272 238 191 101	 n/a	 323 – 343 280 – 294 268 – 278 235 – 245 184 – 198 100 – 104	 n/a
3. Smooth Pursuit – Horizontal 0.1Hz	Velocity gain	0.78	1.07	0.76 - 0.80	1.07 - 1.08
	Asymmetry (%)	-8.80	7.53	(-9.91) – (-8.17)	7.26 - 7.91
	Position gain	0.96	1.04	0.95 - 0.96	1.04 - 1.04
	Saccadic component (%)	n/a	35	n/a	34-37
Smooth Pursuit - Horizontal 0.75 Hz	Velocity gain	0.62	1.08	0.58 - 0.71	1.08 - 1.09
	Asymmetry (%)	-8.93	9.00	(-14.52) – (-5.74)	8.05 - 9.93
	Position gain	0.79	1.10	0.77 - 0.82	1.09 - 1.12
	Saccadic component (%)	n/a	37	n/a	34-40
4. Smooth Pursuit - Vertical 0.1 Hz	Velocity gain	0.69	1.07	0.64 - 0.71	1.06 – 1.09
	Asymmetry (%)	-12.36	11.46	(-13.79) – (-11.62)	9.91 - 13.50
	Position gain	0.95	1.07	0.94 – 0.95	1.06 – 1.07
	% saccadic component	n/a	32	n/a	29 - 34
Smooth Pursuit - Vertical 0.75 Hz	Velocity gain	0.42	1.09	0.37 – 0.43	1.07 – 1.10
	Asymmetry (%)	-23.43	29.01	(-26.75) – (-21.57)	27.78 – 34.11
	Position gain	0.73	1.11	0.73 - 0.75	1.10 - 1.18
	% saccadic component	n/a	52	n/a	50-53

	Table 5-2 CONT. Normative data for OVRT-C tests: 95% RI with 90% CI				
Test	**Variable**	**RI lower limit**	**RI upper limit**	**90% CI for lower limit RI**	**90% CI for upper limit RI**
5. OKN 20deg/s	Average eye velocity – for CCW stimuli (deg/sec)	-20.05	-12.15	(-20.31) – (-19.84)	(-13.00) – (-11.37)
	Average eye velocity – for CW stimuli (deg/sec)	14.56	19.75	13.74 - 14.66	19.58 - 20.84
	Gain	0.66	0.97	0.62 - 0.70	0.96 - 0.98
	Gain Asymmetry (%)	-7.66	10.55	(-10.41) – (-5.42)	9.99 – 12.01
	Area under Vel Fit +(30deg)	5516	n/a	5080 – 5722	n/a
	Area under Vel Fit -(30deg)	n/a	-5956	n/a	(-6161) – (-5735)
OKN 60deg/s	Average eye velocity CCW (deg/sec)	-52.94	-21.15	(-54.01) – (-52.21)	(-22.39) – (-19.69)
	Average eye velocity CW (deg/sec)	24.15	55.93	21.22 – 25.06	54.90 - 56.71
	Gain	0.40	0.90	0.37 - 0.42	0.90 - 0.92
	Gain Asymmetry (%)	-14.54	18.10	(-16.13) – (-12.39)	17.46 – 19.69
	Area under Vel Fit +(30deg)	6289	n/a	5981 - 6415	n/a
	Area under Vel Fit -(30deg)	n/a	-6235	n/a	(-6322) – (-6094)
	Normalized OKN CW velocity gain (normalized at 20deg/sec)	0.47	0.98	0.37 – 0.48	0.95 – 1.01
	Normalized OKN CCW velocity gain (normalized at 20deg/sec)	0.45	0.95	0.40 – 0.48	0.92 – 1.03
6. Subjective Visual - Vertical (SVV)	Mean error (deg)	-2.96	2.96	(-3.00) – (-2.64)	2.81 - 3.35
7. Subjective Visual – Horizontal (SVH)	Mean error (deg)	-2.95	2.95	(-3.27) – (-2.74)	2.33 - 3.14
8. Sinusoidal Harmonic Acceleration (SHA) 0.02Hz	Gain average	0.21	0.67	0.2 - 0.22	0.61 - 0.73
	Asymmetry (%)	-20	25	(-21) - (-17)	22 - 29
	Phase (deg)	10.28	34.84	8.6 - 12.16	31.62 - 39.26
Sinusoidal Harmonic Acceleration (SHA) 0.64Hz	Gain average	0.29	0.83	0.28 - 0.32	0.8 - 0.87
	Asymmetry (%)	-17	15	(-22) – (-15)	11 - 19
	Phase (deg)	-6.46	13.56	(-8.57) – (-4.15)	12.89 - 15.15

	Table 5-2 CONT. Normative data for OVRT-C tests: 95% RI with 90% CI				
Test	**Variable**	**RI lower limit**	**RI upper limit**	**90% CI for lower limit RI**	**90% CI for upper limit RI**
9. Visual Enhancement 0.64Hz	Gain average	0.77	1.09	0.71 - 0.79	1.08 - 1.10
	Asymmetry (%)	-2.80	3.97	(-2.94) – (-2.00)	3.16 – 5.03
	Phase (deg)	-3.51	3.61	(-4.52) – (-2.94)	2.99 - 4.29
10. Visual Suppression 0.64Hz	Gain average	0.08	0.25	0.07 - 0.08	0.24 - 0.27
	Asymmetry (%)	-21.85	22.25	(-23.37) – (-18.11)	19.27 – 25.68
	Phase (deg)	-7.18	31.74	(-15.21) – (-5.4)	30.48 - 32.34
11. crHIT	Gain	0.89	1.03	0.87 - 0.9	1.02 - 1.04
	Asymmetry (%)	-4.42	4.35	(-5.07) – (-3.94)	3.91 - 4.91
12. Visual Reaction Time	Latency (msec)	n/a	343	n/a	335 – 350
13. Auditory Reaction Time	Latency (msec)	n/a	316	n/a	306– 330
	Female - Latency (msec)	n/a	336	n/a	320 – 347
	Male - Latency (msec)	n/a	305	n/a	296 – 317
14. Saccade and Reaction Time	**Saccade variables:**				
	Latency (msec)	n/a	0.29	n/a	0.28 – 0.30
	Accuracy (%)	74	101	65 – 75	100 – 105
	Final accuracy (%)	79	106	72 - 82	103 - 112
	Motor response variables:				
	Latency mean (sec) – for Left Button I-PAS™	n/a	0.65	n/a	0.61 – 0.76
	Latency mean (sec) – for Right Button I-PAS™	n/a	0.65	n/a	0.57 – 0.78
	Latency mean (sec) – for Left Button NOTC	n/a	0.76	n/a	0.74 – 0.76
	Latency mean (sec) – for Right Button NOTC	n/a	0.74	n/a	0.72 – 0.75
15. Predictive Saccades	Percentage predicted (%)	17	n/a	14-17	n/a
16. Antisaccades	Error Rate (%) = % of pro-saccade errors	0	50	0 – 0	50.00 –50.00

n/a – limit is not of clinical interest
Negative numbers reflect the direction of the eye movement.

c) Non-Clinical Performance Data

Software Verification and Validation Testing

Verification testing consisted of verification of the software requirements and hardware requirements. Validation testing was performed to ensure that users were able to properly install, uninstall and use the I-Norm 100_18-45 and that the user interface was operating as intended, i.e. displaying norm values as intended. The verification and validation test results confirm that the I-Portal® devices with the added I-Norm 100_18-45 performs as intended.

Risk Analysis

The addition of I-Norm 100_18-45 can pose a new risk, i.e. misinterpretation of the data if used for subjects outside the 18-45 age interval. This risk is mitigated by adding a warning label in the manual:

WARNING: "I-Norm 100_18-45 is applicable to subjects only in the 18-45 age range. Use of this database for subjects whose age is not within the 18-45 range may result in erroneous information. PLEASE CHECK THE AGE OF THE SUBJECT TO ENSURE THE DESIRED AGE RANGE."

The clinicians can chose to use this normative database as well as their own normative datasets.

The addition of **I-Norm 100_18-45** to the existing VEST™ software running on I-Portal® devices did not identify any other unacceptable residual risks nor increase to the overall I-Portal® devices risk profile as they were originally cleared on 08/06/2009 (K083603), 07/08/2015 (K143607) and 11/22/2017 (K171884).

VIII. Substantial Equivalence

The I-Portal® devices with added I-Norm 100_18-45 are substantially equivalent to the predicate I-Portal® devices: have the same intended use, technological characteristics and principles of operation, function, material, and energy source. The only difference is a choice of presenting patient's test data in the context of a database of known normal subjects. Clinical data included in this application support the change in the new indication for use. The newly identified risk of potential misinterpretation of the data if used for subjects not in the age range from which the normative data was constructed is mitigated by adding a warning label. The technological differences do not present any new issues of safety or effectiveness, which is supported by performance data.

Technological comparisons and clinical testing demonstrate that the I-Portal® devices with I-Norm 100_18-45 are functionally equivalent to their predicate devices.

IX. Conclusion

The information provided in this submission supports safety and effectiveness of the I-Portal® NOTC, VNG and I-PAS™ devices with added I-Norm 100_18-45 for their intended use and demonstrates that the devices are substantially equivalent to their predicates.