December 19, 2024

Vivosonic Inc
Trevor Rocheleau
Regulatory and Quality Assurance Manager
222-5535 Eglinton Avenue West
Toronto, ON M9C 5K5
Canada

Re: K242954
Trade/Device Name: Integrity V500 ("Integrity", "Integrity with VEMP")
Regulation Number: 21 CFR 882.1900
Regulation Name: Evoked Response Auditory Stimulator
Regulatory Class: Class II
Product Code: GWJ
Dated: September 25, 2024
Received: September 25, 2024

Dear Trevor Rocheleau:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242954

Device Name
Integrity V500 ("Integrity", "Integrity with VEMP")

Indications for Use *(Describe)*
The Integrity with VEMP provides testing that is intended to assist in the assessment of vestibular function. The target patient population ranges from school age children to geriatric adults who can complete the testing tasks. The Integrity with VEMP is intended to be used by a variety of professionals, such as clinical practitioners specialized in balance disorders, Audiologists, and Otolaryngologists (ENT doctors) with prior knowledge of the medical and scientific knowledge about the VEMP procedure.

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
K242954

1. SUBMISSION INFORMATION

Date of preparation:	September 24, 2024
Submitter Information:	Vivosonic Inc 222-5535 Eglinton Avenue West Toronto, ON, M9C 5K5 Canada Telephone: +1 (416) 231-9997 Fax: +1 (416) 231-2289
Contact Person:	Mr. Trevor Rocheleau Regulatory and Quality Assurance Manager Telephone: +1 (416) 231-9997 ext 227 Email: trevor.rocheleau@vivosonic.com

2. DEVICE INFORMATION

Device Name:	Integrity V500
Device Trade Name:	Auditory Evoked Response Stimulator
Device Identification Codes:	V500
Classification Name:	Stimulator, Auditory, Evoked Response
Device Class	Class II (According to 21 CFR 882.1900
Product Code Class	GWJ

3. PREDICATE DEVICE

Predicate Device:	Eclipse with VEMP
Manufacturer:	Interacoustics
510(k) No.	K162037
Date Cleared	March 23, 2017

4. REFERENCE DEVICE

Predicate Device:	Integrity, Model V500
Manufacturer:	Vivosonic Incorporate
510(k) No.	K043396
Date Cleared	January 24, 2005

5. DEVICE DESCRIPTION

VEMP (Vestibular Evoked Myogenic Potential) is a short latency response generated either from sternocleidomastoid muscle (cVEMP) or oblique muscle (oVEMP) which is typically evoked by high level acoustic or vibratory stimulation. VEMP is a non-invasive test that is used for diagnosis of vestibular disorders such as superior canal dehiscence, Menier's disease, vestibular neuritis, and, among others. VEMP test can be done in clinics (ENT/audiology) and hospitals provided that the users have adequate knowledge and background about underlying process of VEMP and recording auditory evoked responses.

The Integrity V500 is indicated for auditory evoked potential testing. "Integrity with VEMP" (this submission) is the addition of the VEMP test modality to the Integrity V500. The Integrity V500 is an auditory evoked auditory system response and Integrity with VEMP is an auditory evoked vestibular system response. Since the vestibular system is connected to the auditory system, a loud stimulus to the auditory system also simultaneously stimulates the vestibular system. However, the evoked signals are measured at different electrode sites. It is important to note that the methods of stimulation and data acquisition are the same for the VEMP modality as for the ABR modality (one of the Integrity V500's auditory evoked testing modalities), with differences being in electrode montage and patient's physical state. As such, it is possible to also get a VEMP response while testing in the Integrity V500's ABR modality.

Integrity with VEMP is a PC based device which uses the same hardware and similar software for evoking the stimulus, collecting the response, processing the data, and displaying the outcome on the screen as does the Integrity V500. The hardware used are: a VivoLink (patient interface device), air and bone conduction transducers (to stimulate the vestibular system), CV-Amp (bio-amplifier), and a computer. The response from the muscle is picked up by a bio-amplifier attached to the neck (for cVEMP) or under eyes (for oVEMP) and forehead with electrodes. The data is then sent to the VivoLink for pre-processing and then transferred to the PC via Bluetooth connection for full processing using the algorithm designed for VEMP processing. Through the test, the processed sweeps are filtered using the filter setting defined by the user and the averaged response is shown on the screen.

The primary diagnostic component of a VEMP measurement is the comparison of the amplitude of the primary peak of the VEMP response between right and left sides, defined as an asymmetry ratio, where a significant amount of asymmetry is indicative of a vestibular disorder. The amplitude of the vestibular response peaks is also dependent on the contraction level of the muscles involved in the recording. To minimize the muscular response biasing the result, it is important to have equal contraction levels for both sides; this is especially physically challenging to generate equivalent neck contractions needed for

cVEMP. To overcome this issue, two key features were added to the Integrity with VEMP compared to Integrity V500: a biofeedback EMG monitor (which displays real-time muscular activity) and VEMP response normalization (scaling based on muscular contraction levels). The EMG monitors can be used as a guidance to the clinicians and patients for the level of muscle contraction. Normalization automatically scales the recorded sweeps based on the energy of the corresponding EMG which helps to compensate for imbalance contraction from the two sides.

6. INDICATIONS OF USE

The Integrity with VEMP provides testing that is intended to assist in the assessment of vestibular function. The target patient population ranges from school age children to geriatric adults who can complete the testing tasks. The Integrity with VEMP is intended to be used by a variety of professionals, such as clinical practitioners specialized in balance disorders, Audiologists, and Otolaryngologists (ENT doctors) with prior knowledge of the medical and scientific knowledge about the VEMP procedure.

7. TECHNOLOGICAL CHARACTERISTICS

The Integrity with VEMP consists of a battery-operated patient-interface device (Vivolink), Bio-amplifier, transducer, electrodes, and PC (laptop). Stimulus and data collection is done via Vivolink, while processing of the data is done through the VEMP software on the PC.

8. SAFETY AND EFFECTIVENESS-COMPARISON TO PREDICATE DEVICE AND REFERENCE DEVICE

Predicate Device

The Integrity V500 with VEMP and Interacoustics' Eclipse with VEMP (K162037) have the same intended use and similar technical characteristics in terms of stimulators and electrodes (i.e. patient contact). However, the Eclipse with VEMP is powered by mains whereas the Integrity is battery powered. They both have the biofeedback and waveform normalization.

Reference Device

The reference device is the previous iteration of Integrity V500 (K043396).

The Integrity V500 and the Integrity V500 with VEMP use the same physical hardware. As such, they have the same technical characteristics in terms of design, material, chemical composition, and energy source. The only difference is software functionalities, such as biofeedback (which can be done on an external monitor) and waveform normalization, based on muscle contraction, all of which are designed to streamline the VEMP testing itself.

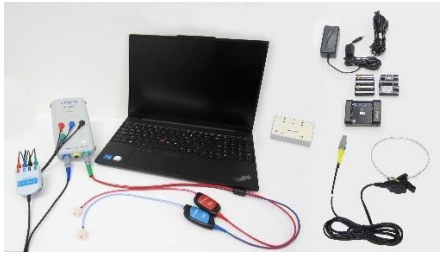
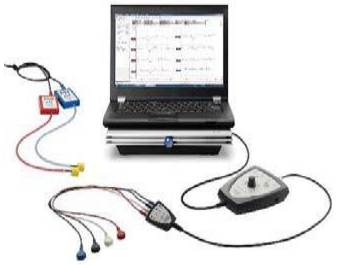
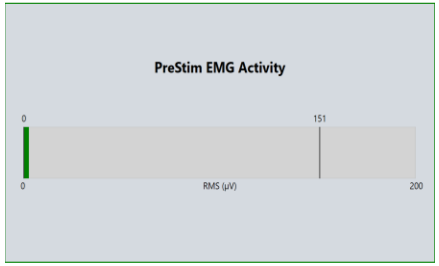
9. PRODUCT COMPARISONS CHARTS SUMMARY

The primary comparison device used for this submission is Eclipse with VEMP (K162037) as the VEMP modality has the same indications for use as the Integrity with VEMP.

The reference device is the previous iteration of Integrity V500 (K043396). Integrity V500 is not indicated for vestibular testing. However, it is an AEP system that uses the same stimuli and data collection, just different electrode montage and patient position. Since it uses the same hardware as the Integrity V500 with VEMP, it is an appropriate device to support the technical characteristics and validation of the Integrity with VEMP.

Description	Integrity V500 with VEMP (K24954)	Predicate Device Eclipse with VEMP (K162037)	Reference Device Integrity V500 (K043396)	Equivalence
Intended Purpose				
Indication for use	The Integrity with VEMP provides testing that is intended to assist in the assessment of vestibular function. The target patient population ranges from school age children to geriatric adults who can complete the testing tasks. The Integrity with VEMP is intended to be used by a variety of professionals, such as clinical practitioners specialized in balance disorders, Audiologists, and Otolaryngologists (ENT doctors) with prior knowledge of the medical and scientific knowledge about the VEMP procedure.	The Eclipse with VEMP is intended for vestibular evoked myogenic potential testing to assist in the assessment of vestibular function. The target population for Eclipse with VEMP includes patients aged from 8 years and up.	Integrity V500 is indicated to measure or determine cochlear function testing or auditory evoked potential testing as an aid in detecting hearing loss and lesions in auditory pathway.	Similar Clinical performance testing included school aged children.

Physiological Features				
Bio Signal	Evoked Potential	Evoked Potential	Evoked Potential	Same
Electrode Montage	**cVEMP**: non-inverting electrodes on head, inverting electrodes on sternocleidomastoid (left and right) **oVEMP**: non-inverting electrodes on head, inverting electrodes under the 2 eyes.	In total 4 electrodes: 1 in each SCM which is for both recording and monitoring via the built-in software EMG monitor, 1 at the clavicle junction, 1 at lower forehead.	For Auditory evoked potential, non-inverting electrodes on head and inverting electrodes on mastoid/earlobe	The configuration of the electrodes is subjective. The differences between the two systems do not raise any safety or effectiveness issues.
Stimulation Target	Vestibular System	Vestibular System	Auditory Pathway	Same
Hardware				
Configuration (Hardware)	Integrity V500 is a PC based system with external hardware (Vivolink) and accessories (amplifier, transducers, electrodes). Plus, an additional external monitor for biofeedback.	Eclipse platform connected to PC (PC-Based system with external hardware platform and peripherals (USB interface)).	Integrity V500 is a PC based system with external hardware (Vivolink) and accessories (amplifier, transducers, electrodes)	There are physical differences between eclipse and Integrity. But the functionality is the same. Clinical performance testing showed similar outcomes for the eclipse and integrity devices.
Pre-Amplifier	2 channels	2 channels	2 channels	Same

Photo				Same functionality
Biofeedback Monitor	The visual monitor is used. Below the range is shown in blue, within the range in green, and above the range in red. 	A visual or acoustic VEMP monitor. The visual VEMP monitor is displayed on an external screen and indicates below range (low), in range for recording (good) and outside range (high). 	N/A	Similar functionality shows the ranges in colors between eclipse and Vivosonic. The minor differences don't have any impact on safety and effectiveness.
Compatible Transducers	Air Conduction (AC) Bone Conduction (BC)	Air Conduction (AC) Bone Conduction (BC)	Air Conduction (AC) Bone Conduction (BC)	Same
Power	AC line for the PC. Battery for the Vivolink	AC power	AC line for the PC. Battery for the Vivolink	Same
Implementation Details				
Environment of Use	Clinics (Audiology/ENT) Hospitals	Hospital/Clinics	Clinics (Audiology/ENT) Hospitals	Same

Target Population	School Age Children/Adult	From age 8 and up and adults.	Infant/Adult	Similar for eclipse and Vivosonic VEMP Clinical performance testing included school aged children.
Tests Performed	Vestibular Evoked Myogenic Potential (VEMP) only in this module	Auditory Brainstem Response (ABR) Electrocochleography (ECochG) Auditory Middle Latency Response (AMLR) Auditory Late Response (ALR) P300/Mismatch negativity (MMN) Auditory Steady State Response (ASSR) Vestibular Evoked Myogenic Potential (VEMP)	Auditory Brainstem Response (ABR) Electrocochleography (ECochg) Cortical Middle Latency/Late Latency Response (MLR/LLR) Auditory Steady State Response (ASSR)	VEMP tests are same between eclipse and Vivosonic
Polarity (Stimulus)	Rarefaction, Condensation, Alternating, Alternating-Split	Rarefaction, Condensation, Alternating	Rarefaction, Condensation, Alternating, Alternating-Split	Same
Stimulus Types	Click, Tone Burst	Click, Tone burst, Narrow Band Chirp, Wide Band Chirp	Click, Chirp, Tone Burst	Same
Evaluation of results	Manually / Subjective	Manually / Subjective	Manually / Subjective	Same
EMG Scaling	Yes	N/A	Yes	Same
Automatic asymmetry calculation	Yes	Yes	Yes (Interaural differences table)	Same

Results Interpretation	The device presents the results to the ENT specialists or Audiologist. No diagnosis is done by the device.	The device presents the results to the ENT specialists or Audiologist. No diagnosis is done by the device.	N/A	Same

It must be noted that there are some hardware and software differences between predicate device and the Vivosonic Integrity V500 with VEMP device. However, these differences do not affect safety and effectiveness.

With the Vivosonic system, the stimulation and the response detection (via electrodes) are handled by the battery-operated patient interface module (Vivolink). The Vivolink communicates wirelessly (Bluetooth) with the clinician's PC. The bio-amplifier (CV-Amp) is optimized for VEMP testing, including a fixed hardware gain and filtering.

With the predicate device, the stimulation and the response detection (via electrodes) are connected directly to the device's primary module. This module is directly powered by the mains and directly wired to the clinician's PC. Its bio-amplifier is general for all evoked response testing.

Although the software has the same functionality, the GUI for the Integrity's VEMP module is based on the Integrity's previous ABR module, whereas the predicate device is based on its own previous ABR module.

Performance testing was conducted to evaluate differences in hardware and software, and the results support substantial equivalence between the two systems.

10. SUMMARY OF NON-CLINICAL TESTING

Bench verification and testing demonstrates compliance with system and software specifications. There are no changes to the hardware including electrical safety or EMC compared to the already cleared reference device, the Integrity V500 (K043396). As such, there is no need for hardware bench testing. Software validation and risk analysis was performed to confirm the proper functions of the VEMP protocol. Risk management indicated that there are no critical tasks; as such a human factors study was not necessary to be performed.

11. SUMMARY OF CLINICAL TESTING

VEMP is a well-documented test for evaluating the vestibular functions. Integrity with VEMP includes biofeedback EMG monitor and VEMP response normalization feature which facilitate the control of the muscle contraction and compensate for imbalance contraction from the two sides. The objective of the clinical studies was to prove (a) the substantial equivalency between it and its predicate device (Interacoustics Eclipse (K162037)) and (b) shows its test-retest reliability and reproducibility.

Study 1 was conducted to prove substantial equivalency between Integrity with VEMP and FDA cleared device Interacoustics Eclipse (K162037) which is currently in the market. **Study 2** was conducted to prove the reliability and reproducibility of the new Integrity with VEMP and to compare the data with industry-accepted standards.

Study 1

The parameters of the conducted tests were as follows

- 13 normal adult participants for cVEMP and 9 adult participants
- Integrity VEMP and Interacoustics Eclipse was used to record and analyze cVEMP and oVEMP responses.

Parameters	Values
Stimulus Level	105 dB nHL
Stim rate	4.7/sec
Filter (HP cutoff)	10 Hz
Filter (LP cutoff)	300 Hz
Type of window	Blackman (4 cycle)
Stimulus	TB 500 Hz
Polarity	Rarefaction
Transducer	Air Conduction
Number of stimuli	0-200
EMG Controlled Pre-Stim cVEMP only - Integrity with VEMP	50 (minimum)-150 µV (maximum) rms
Biofeedback	Verbal instructions from the clinician

The latencies and amplitudes were analyzed for both the cVEMP and oVEMP and compared with literature norms. Reliability was analyzed using intraclass correlation (ICC) coefficient analysis.

Comparing the performance of the cVEMP data recorded by Integrity with VEMP and Eclipse (Predicate device).

cVEMP	Integrity VEMP μ ± σ		Interacoustics μ ± σ		Norms from Literature (range)	ICC	
	Right	Left	Right	Left		Right	Left
P1 [ms]	15.6 ± 1.3	15.8 ± 1.4	14.7 ± 1.2	15.1 ± 1.5	11 to 17 ms	0.72	0.91
N1 [ms]	23.5 ± 1.6	23.9 ± 1.5	23.6 ± 1.4	23.7 ± 1.8	18 to 27ms	0.95	0.80
P1-N1 [μV]	209.6 ± 105.3	198.7 ± 106	195.5 ± 54.4	168.8 ± 48.8	28 to 300 (μV)	0.67	0.71

Comparing the performance of the oVEMP data recorded by Integrity with VEMP and Eclipse (Predicate device).

oVEMP	Integrity VEMP μ ± σ		Interacoustics VEMP μ ± σ		Norms from Literature (range)	ICC	
	Right	Left	Right	Left		Right	Left
N1 [ms]	11.2 ± 0.8	11.4 ± 0.9	10.2 ±1.1	10.4 ±1.1	9 to 19 ms	0.63	0.78
P1 [ms]	15.9 ± 1.7	16.3 ±1.6	15.2 ± 1.7	15.2 ±1.6	12 to 22 ms	0.89	0.76
N1-P1 [μV]	17.4 ± 8.5	17.3 ± 8.3	16.7 ± 10.6	14.1 ± 6.6	2 to 45 (μV)	0.90	0.91

The study 1 results meet our substantial equivalency criteria between the two systems. This is concluded based on (1) both systems' results are consistent with those found in the Literature, and (2) the statistical analysis between the two systems' results shows good to excellent reliability.

Study 2

Testing was conducted at two sites (one in Canada and one in the United States)

- US site: 33 normal hearing adults for cVEMP tests (30 male, 3 female) and 17 normal hearing adults for oVEMP test (2 male, 15 female) with air conduction transducer (AC).
- Canada Site: 9 school-age normal hearing children for cVEMP subjects with bone conduction transducer (BC) and 8 pre-school age normal hearing children for cVEMP subjects with air conduction transducer (AC).

Parameters	Values
Min number of runs per ear 2 repeatable waveforms	Min number of runs per ear 2 repeatable waveforms
Stimulus Level	95 dB nHL
Stim rate	4.7/sec
Filter (HP cutoff)	10 Hz
Filter (LP cutoff)	300 Hz
Type of window	Blackman (4 cycle)

Stimulus	TB 500 Hz
Polarity	Rarefaction
Transducer	Air Conduction
Number of stimuli	0-200
EMG Controlled Pre-Stim cVEMP only - Integrity with VEMP	50 (minimum)-150 µV (maximum) rms

The mean, median, and IQR (75th – 25th percentile) values of the tested populations correlation between the VEMP waveforms obtained from two tests (a) in one session (for test-retest reliability) and (b) in two sessions separated by 24 to 72 hours (for reproducibility) should be similar to those from other products in the industry ("510(K) document for Eclipse with VEMP (K162037)"). High mean and median values indicate a high degree of repeatability, whereas a low value for IQR also indicates a large number of correlation coefficients are clustered near the median ("510(K) document for Eclipse with VEMP (K162037)")

- From "510(K) document for Eclipse with VEMP (K162037)", industry acceptable test-retest repeatability and reproducibility for air conduction VEMP is assumed for a mean of correlation values ≥ 0.879 and for an IQR ≤ 0.111.

Test-Retest Reliability based on the correlation of waveforms taken from one session .

Test-Retest Reliability	**cVEMP (5 – 35 ms) Air Conduction**	**oVEMP (4 – 20 ms) Air Conduction**	**cVEMP (5 – 35 ms) Bone Conduction**
Mean (µ)	0.92	0.89	0.92
Median	0.94	0.89	0.92
Standard Deviation (σ)	0.05	0.05	0.05
IQR (75^{th} – 25^{th} percentile)	0.07	0.08	0.12

The mean values are all ≥ 0.879 and the air conduction values all have an IVR ≤ 0.111. The slight increase in IVR for bone conduction (IVR = 0.12) is understandable given the greater variability associated with bone conduction in general. As such, the Test-Retest Reliability is within industry standards ("510(K) document for Eclipse with VEMP (K162037)").

Test-Retest Reproducibility based on the correlation of waveforms taken from two sessions separated by 24 to 72 hours

Reproducibility	**cVEMP (5 – 35 ms) Air Conduction**	**oVEMP (4 – 20 ms) Air Conduction**
Mean (µ)	0.92	0.89
Median	0.93	0.87
Standard Deviation (σ)	0.05	0.06
IQR (75^{th} – 25^{th} percentile)	0.08	0.11

The mean values are all ≥ 0.879 and the air conduction values all have an IVR ≤ 0.111. As such, the Test-Retest Reproducibility is within industry standards ("510(K) document for Eclipse with VEMP (K162037)"). Study 2 results meet our criteria to prove the reliability and reproducibility of the new Integrity VEMP device. This is concluded based on the reliability values and the reproducibility values by Integrity VEMP is similar to those from other products in the industry ("510(K) document for Eclipse with VEMP (K162037)"). We conclude that Integrity VEMP has good test-retest reliability and reproducibility.

12. CONCLUSIONS

Integrity with VEMP has the same intended use and similar indications for use as the predicate device, Eclipse with VEMP. Integrity with VEMP also has the similar technical characteristics as its reference device, Integrity with AEP. The addition of biofeedback EMG monitor and VEMP response normalization to its software helps to control the muscle contraction and compensate for imbalance contraction from the two sides during VEMP testing. Non-clinical testing of the reference device supports the safety and effectiveness of the Integrity with VEMP. Clinical performance testing demonstrates substantial equivalence with the predicate device, Eclipse with VEMP. It also demonstrates that test-retest reliability and reproducibility of Integrity with VEMP is within industry accepted values as inferred from the "510(K) document for Eclipse with VEMP (K162037)". Therefore, Integrity with VEMP can be considered substantially equivalent to the predicate devices. Integrity with VEMP is a clinical tool for healthcare professionals such as audiologists and ENT doctors to evaluate vestibular disorders using both cVEMP and oVEMP tests along with the other vestibular tests battery.