March 25, 2021

Vista LifeSciences, Inc.
Margaret Molloy
President and CEO
7375 S. Peoria St. Suite 210
Englewood, Colorado 80112

Re: K201376
Trade/Device Name: ANAM Test System
Regulation Number: 21 CFR 882.1471
Regulation Name: Computerized Cognitive Assessment Aid for Concussion
Regulatory Class: Class II
Product Code: POM
Dated: February 11, 2021
Received: February 19, 2021

Dear Margaret Molloy:

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,

Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201376

Device Name
ANAM Test System

Indications for Use *(Describe)*
The ANAM® Test System: Military, Military Expanded, Core, and Sports Batteries are intended for use as computer-based neurocognitive test batteries to aid in the assessment and management of mild traumatic brain injury. The ANAM Test System: Military, Military Expanded, Core, and Sports Batteries are neurocognitive test batteries that provide healthcare professionals with objective measure of neurocognitive functioning as assessment aids and in the management of mild traumatic brain injury in individuals ages 13-65.

The ANAM Test System should only be used as an adjunctive tool for evaluating cognitive function.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the ANAM Test System is provided below.

Device Common Name:	Computerized Cognitive Test
Device Proprietary Name:	ANAM Test System
Applicant:	Vista LifeSciences, Inc. PO Box 4670 Parker CO 80134 Phone: 888.733.8804 Ext. 1 www.vistalifesciences.com
Contact:	Margaret E. Molloy CEO and President Vista LifeSciences, Inc. PO Box 4670 Parker CO 80134 Phone: 888.733.8804 Ext. 4 Email: memolloy@vistapartners.com
Prepared by:	Lori White Quality Systems Program Manager Vista LifeSciences, Inc. PO Box 4670 Parker CO 80134 Phone: 888.733.8804 Ext. 1 Email: lori.white@vistalifesciences.com
Date Prepared:	March 22, 2021
Classification Regulation:	882.1471 Computerized Cognitive Assessment Aid for Concussion
Panel:	Neurology
Product Code:	POM
Predicate Device:	DEN150037, ImPACT

Indication for Use:

The ANAM® Test System: Military, Military Expanded, Core, and Sports Batteries are intended for use as computer-based neurocognitive test batteries to aid in the assessment and management of mild traumatic brain injury. The ANAM Test System: Military, Military Expanded, Core, and Sports Batteries are neurocognitive test batteries that provide healthcare professionals with objective measure of neurocognitive functioning as assessment aids and in the management of mild traumatic brain injury in individuals ages 13-65.

The ANAM Test System should only be used as an adjunctive tool for evaluating cognitive function.

Device Description:

The ANAM Test System is a software only device that provides clinicians with objective measurements of cognitive performance in populations, to aid in the assessment and management of concussion. ANAM measures various aspects of neurocognitive functioning including reaction time, memory, attention, and spatial processing speed. It also records symptoms of concussion in the test taker.

The software is downloaded from the Vista LifeSciences website and is for use on Dell Inspiron 15 3000 Series or similar Windows PC model or Android Samsung Galaxy tablet or similar Android device. The hardware is not provided as part of the device but is purchased separately by the user. Each ANAM battery consists of a collection of pre-selected modules that are administered in a sequential manner.

Specific modules included in the ANAM Test System:

1. Questionnaires
    1. Demographics
    2. Mood Scale
    3. Neurobehavioral Symptom Inventory (NSI)
    4. PTSD Checklist (PCL)
    5. Sleepiness Scale
    6. Symptoms Checklist
    7. TBI Questionnaire

Performance Tests

8. Code Substitution – Learning*
9. Code Substitution – Delayed*
10. Go/No-Go*
11. Matching to Sample*
12. Mathematical Processing*
13. Memory Search*
14. Procedural Reaction Time*
15. Simple Reaction Time*
16. Spatial Processing*

*Available for tablet platform.

The tests and questionnaires can be combined into custom batteries or users can choose from pre-configured standardized batteries. The standardized batteries include ANAM Core, ANAM Sports, ANAM Military, and ANAM Military-Expanded. These standardized batteries have fixed test settings and parameters to ensure standardized presentation and enable comparison to normative data.

This 510(k) submission provides evidence demonstrating that the ANAM Test System is substantially equivalent to a POM predicate device and is therefore safe and effective to use following concussion. The ANAM Core, Sports, Military, and Military-Expanded batteries as well as the individual tests comprising these batteries have demonstrated sensitivity to the cognitive effects of concussion and, thus, will serve as the focus of the materials provided herein. In some cases descriptions and features of the entire ANAM Test System have been provided to better facilitate the understanding of the complete system and its many features as a computerized cognitive assessment aid.

Performance Data:

The 510(k) includes the results of numerous studies that have examined the concurrent validity of ANAM as a clinical tool by documenting correlations with traditional neuropsychological tests with both normal and concussed populations. The results of these studies demonstrate that ANAM provides a reliable measure of cognitive function for use as an assessment aid and in the management of concussion and is therefore substantially equivalent to the predicate device.

Substantial Equivalence:

Both the predicate device and ANAM “provide healthcare professionals with objective measure of neurocognitive functioning as an assessment aid and in the management of concussion”. The predicate device does this by measuring verbal and visual memory, visual motor speed, impulse control, and reaction time. ANAM also measures fundamental neurocognitive functions including response speed, attention/concentration, immediate and delayed memory, spatial processing, inhibition, and decision processing speed and efficiency.

The intended use of ANAM is the same as that of the predicate device, namely for use as a computer-based neurocognitive test battery to aid in the assessment and management of concussion.

A technological comparison is provided in the table below.

	Proposed Device	**Predicate Device**
510(k) Number	TBD	DEN 150037
Device Name	ANAM Test System	ImPACT
Submitter	Vista LifeSciences, Inc.	ImPACT Applications, Inc.
Classification Regulation	Class II	Class II
Product Code	POM	POM

	Proposed Device	Predicate Device
Indication	The ANAM® Test System: Military, Military Expanded, Core, and Sports Batteries are intended for use as computer-based neurocognitive test batteries to aid in the assessment and management of mild traumatic brain injury. The ANAM Test System: Military, Military Expanded, Core, and Sports Batteries are neurocognitive test batteries that provide healthcare professionals with objective measure of neurocognitive functioning as assessment aids and in the management of mild traumatic brain injury in individuals ages 13-65. The ANAM Test System should only be used as an adjunctive tool for evaluating cognitive function.	ImPACT is intended for use as a computer-based neurocognitive test battery to aid in the assessment and management of concussion. ImPACT is a neurocognitive test battery that provides healthcare professionals with objective measure of neurocognitive functioning as an assessment aid and in the management of concussion in individuals ages 12-59.
Platform	PC: Dell Inspiron 15 3000 Series or similar Windows laptop computer, Windows 10 operating system. Tablet: Samsung Galaxy Tab A tablet or similar Android device, Android 7.1 – 8.1 operating systems.	Internet browser.
Use Cases	Measures change over time and/or compares performance with normative data.	Measures change over time and/or compares performance with normative data.
Patient Population	Individuals	Individuals
Age of Users	13-65 years	12-59
How Provided	Software only, downloaded	Internet browser

	Proposed Device	Predicate Device
Reporting features	ANAM Performance Report (APR) provides raw scores and standard scores (calculated with the normative database) for each test within the battery. APR also yields the ANAM Composite Score (ACS) summarizing performance across the test battery. The ACS is a summed T-score that is computed relative to the summed T-score of a normative control group. The ACS is reported in standard deviation units. Reliable Change Indices (RCI) are calculated and displayed for each individual test to capture change in performance between a specified test session and a previous test session (e.g. baseline).	ImPACT Clinical Report provides composite scores for tests in the battery including Verbal Memory Composite, Visual Memory Composite, Visual Motor Speed Composite, Reaction Time Composite, Impulse Control Composite, Total Symptom Score, and Cognitive Efficiency Index (CEI). Reliable Change Indices (RCI) are calculated and displayed to capture change in performance between a specified test session and a previous test session (e.g. baseline).
Results Interpretation	Clinical interpretation of the results includes comparison with the normative database and/or previous test sessions. ANAM provides raw scores, standard scores, and reliable change indices for each test. Performance on sub-tests are evaluated individually as well as within the context of the entire test battery.	Clinical interpretation of the results includes comparison with the normative database and/or previous test sessions. ImPACT provides raw scores and percentile scores. Performance on sub-tests are evaluated individually and presented as composite scores.

Summary / Conclusion of Substantial Equivalence Rationale

Although there are some differences in the modules between ANAM and the predicate device, the performance testing demonstrates that ANAM provides a reliable measure of neurocognitive functioning to aid in the assessment and management of concussion and is therefore substantially equivalent to the predicate device.