March 22, 2018

The TOVA Company
Chris Holder, CEO
2828 SW Corbett Ave, Suite 128
Portland, Oregon 97201

Re: K173915
Trade/Device Name: Test of Variables of Attention (T.O.V.A.) version 9.0
Regulatory Class: Unclassified
Product Code: LQD
Dated: December 20, 2017
Received: December 22, 2017

Dear Chris Holder:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K173915

Device Name
Test of Variables of Attention (T.O.V.A.) version 9.0

Indications for Use *(Describe)*
The Test of Variables of Attention (T.O.V.A.) provides healthcare professionals with objective measurements of attention and inhibitory control. The visual T.O.V.A. aids in the assessment of, and evaluation of treatment for, attention deficits, including attention-deficit/hyperactivity disorder (ADHD). The auditory T.O.V.A. aids in the assessment of attention deficits, including ADHD. T.O.V.A. results should only be interpreted by qualified professionals.

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

Date: March 19th, 2018

510(k) Submitter: **The TOVA Company**
2828 SW Corbett Ave suite 128
Portland, OR 97201 USA
Contact Person: Chris Holder
Tel 360-661-2899
Email: chris@thetovacompany.com

Trade Name: **Test of Variables of Attention (T.O.V.A.) version 9.0**
Common name: Continuous Performance Test (CPT)
Product Code: LQD
Classification name: Recorder, attention task performance
Device class: Unclassified

Predicate Device: QbTest from Qbtech AB (K133382)

Device Description: The Test of Variables of Attention (T.O.V.A.) is an accurate and objective continuous performance test (CPT) that measures the key components of attention and inhibitory control. The T.O.V.A. is used by qualified healthcare professionals in the assessment of attention deficits, including attention-deficit/hyperactivity disorder (ADHD), in children and adults. In addition, the visual T.O.V.A. is used to evaluate treatment for attention deficits, including ADHD.

The T.O.V.A. is a culture- and language-free, sufficiently long computerized test that requires no left/right discrimination or sequencing. Responses to visual or auditory stimuli are recorded with a specially designed, highly accurate (±1 ms) microswitch. The T.O.V.A. calculates response time variability (consistency), response time (speed), commissions (impulsivity), and omissions (focus and vigilance). These calculations are then compared to a large age- and gender-matched normative sample (over 1,700 individuals for the visual test, and over 2,500 individuals for the auditory test), as well as to a sample population of individuals independently diagnosed with ADHD. These comparison results are used to create an immediately available, easy-to-read report.

The T.O.V.A. system includes: a USB flash drive with software installer for Mac and Windows PCs, a T.O.V.A. USB device, a T.O.V.A. Microswitch, an Installation Guide, a User's Manual, a Clinical Manual, and accessory cables (USB, VGA, and audio cables).

Indications for Use: The Test of Variables of Attention (T.O.V.A.) provides healthcare professionals with objective measurements of attention and inhibitory control. The visual T.O.V.A. aids in the assessment of, and evaluation of treatment for, attention deficits, including attention-deficit/hyperactivity disorder (ADHD). The auditory T.O.V.A. aids in the assessment of attention deficits, including ADHD. T.O.V.A. results should only be interpreted by qualified professionals.

Technological Characteristics:

The T.O.V.A**.** consists of the TO.V.A. USB Device, the T.O.V.A. Microswitch, and a USB flash drive with software for use on a Mac or Windows PC. The T.O.V.A. has been designed and tested to be safe and effective when used by qualified professionals.

Performance Data:

The T.O.V.A. has been verified and validated in accordance with design controls. The T.O.V.A has passed testing for safety and essential performance under IEC 60601-1:2005 “Medical electrical equipment - Part 1: General requirements for basic safety and essential performance” and electromagnetic compatibility under IEC 60601-1-2:2014 “Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests". In all instances, the T.O.V.A. functioned as intended and the performance observed was as expected. Testing for safety and essential performance for electrical and electromagnetic capability is identical to the T.O.V.A. cleared under K170082.

Test	Test Method Summary	Results
IEC 60601-1:2005 “Medical electrical equipment - Part 1: General requirements for basic safety and essential performance”	A third-party test facility (UL, Inc.) tested the T.O.V.A. 9 system to IEC 60601-1:2005.	The T.O.V.A. passed the state of the art for electrical safety and functional testing. Although no such testing was done for the QbTest, it met the safety and functional testing required for 510(k) clearance in 2014. Thus, the T.O.V.A. has equivalent safety and functionality testing to the QbTest.
IEC 60601-1-2:2014 “Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests"	A third-party test facility (Element, Inc.) tested the T.O.V.A. 9 system to IEC 60601-1-2:2014.	The T.O.V.A. passed the state of the art for electromagnetic compatibility and electromagnetic immunity testing. Although no such testing was done for the QbTest, it met the safety and functional testing required for a traditional 510(k) premarket notification in 1989. Thus, the T.O.V.A. has equivalent electrical performance to the QbTest.
T.O.V.A. Verification Testing	The T.O.V.A. system was fully tested (verified) by the TOVA Company.	The T.O.V.A. functioned as intended, passing all major verification tests, and was FDA cleared under K170082. Since the QbTest was cleared under K133382, T.O.V.A. and QbTest meet equivalent verification testing requirements.

Substantial Equivalence:

The T.O.V.A. is substantially equivalent to the QbTest that was cleared under submission number K133382. The T.O.V.A. has similar intended use and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the T.O.V.A. and its predicate devices raise no new issues of safety or effectiveness. A detailed comparison is shown below.

	QbTest	Test of Variables of Attention (T.O.V.A.)
510(k) Number	K133382	K170082
FDA CODE	LQD	LQD
FDA Class	Unclassified	Unclassified
Intended Use	QbTest provides clinicians with objective measurements of hyperactivity, impulsivity, and inattention to aid in the clinical assessment of ADHD and in the evaluation of treatment interventions in patients with ADHD. QbTest results should be interpreted only by qualified professionals.	The Test of Variables of Attention (T.O.V.A.) provides healthcare professionals with objective measurements of attention and inhibitory control. The visual T.O.V.A. aids in the assessment of, and evaluation of treatment for, attention deficits, including attention-deficit/hyperactivity disorder (ADHD). The auditory T.O.V.A. aids in the assessment of attention deficits, including ADHD. T.O.V.A. results should only be interpreted by qualified professionals.
Normative study range	Visual: Ages 6 to 60	Visual: Ages 4 to 80. Auditory: Ages 6 to 29.
Norming Data	Normative data are based on 1,307 individuals ages 6 to 60.	Normative data are based on 1,714 (visual) and 2,680 (auditory) individuals ages 4 to 80.
Device Description (510k Summary)	QbTest is a non-invasive test that has been developed to provide: precise quantitative assessment of the capacity of an individual to pay attention to visual stimuli and inhibit impulses. There are three cardinal disturbances in Attention-Deficit Hyperactivity Disorder (ADHD); impaired attention, hyperactivity and impulsivity. QbTest provides an accurate and reproducible measure of an individual's capacity in each of these three domains by utilizing a consistent challenge paradigm coupled with detailed real-time measurements of behavior and performance. The fundamental core of QbTest is a computer-assisted attention and impulse control task and simultaneous recording of activity using an infrared camera for motion measurements. The system consists of the following components: • Client software	The Test of Variables of Attention (T.O.V.A.) is an accurate and objective continuous performance test (CPT) that measures the key components of attention and inhibitory control. The T.O.V.A. is used by qualified healthcare professionals in the assessment of attention deficits, including attention-deficit/hyperactivity disorder (ADHD), in children and adults. In addition, the visual T.O.V.A. is used to evaluate treatment for attention deficits, including ADHD. The T.O.V.A. is a culture- and language-free, sufficiently long computerized test that requires no left/right discrimination or sequencing. Responses to visual or auditory stimuli are recorded with a specially designed, highly accurate (±1 ms) microswitch. The T.O.V.A. calculates response time variability (consistency), response time (speed), commissions (impulsivity), and omissions (focus and vigilance). These calculations are then compared to a large age- and gender-matched normative sample (over 1,700 individuals for the visual test, and over 2,600 individuals for the auditory test), as well as to a sample population of individuals independently diagnosed with ADHD. These comparison results are used to create an immediately available, easy-to-read report.

	QbTest	Test of Variables of Attention (T.O.V.A.)
	• Responder button (also referred to as responder unit) • Infrared camera • Reflective motion marker • User manual • Technical manual • Stimulus card • Camera stand • Measuring tape • QbTest Behavior Rating Scale • In addition, the user must have access to a remote server that generates test reports	The T.O.V.A. system includes: a USB flash drive with software installer for Mac and Windows PCs, a T.O.V.A. USB device, a T.O.V.A. Microswitch, an Installation Guide, a User's Manual, a Clinical Manual, and accessory cables (USB, VGA, and audio cables).
Length of test	15 to 20 minutes.	10.8 to 21.6 minutes.
Continuous Performance Test (CPT)	Yes (Go/No Go task).	Yes (Go/No Go task).
Visual stimuli	Yes (geometric shapes).	Yes (geometric shapes).
Auditory stimuli	None	Yes (tones).
Technology	Software on a Windows PC with a "response unit" microswitch and infra-red camera and reflector headband.	Real-time, microcontroller-based, portable stand-alone unit, with USB connection to a Mac or Windows PC.
Subject response mechanism	"Response Unit" (microswitch).	T.O.V.A. Microswitch.
Timing accuracy	Unknown.	Accurate to ±1 milliseconds.
Statistics gathered	Omissions (false negatives), Commissions (false positives), Response Times, Response Time Variability, Anticipatory Responses, Multiple Responses, Head motion.	Omissions (false negatives), Commissions (false positives), Response Times, Response Time Variability, Anticipatory Responses, Multiple Responses.
Report	1-page graphical report	6-page graphical report
Accessories	Client software, responder unit, Infrared camera, Reflective motion marker, Stimulus card, Camera stand, Measuring tape, QbTest Behavior Rating Scale	T.O.V.A. USB Device, T.O.V.A. Microswitch, USB flash drive, and off-the-shelf USB, audio, and video cables.
Software	Software, updateability unknown.	Firmware and software, fully updateable.
Platforms	Windows PCs running Windows 7 – 10.	Windows PCs running Windows 7 – 10. Mac computers running Mac OS X 10.8 – 10.12
Standards with which the Device Complies	IEC 60601-1: 2012 and IEC 60601-1-2:2014	IEC 60601-1: 2012 and IEC 60601-1-2:2014