K122149

510(k) Summary

Date: 17 July 2012

OCT 17 2012

510(k) Submitter: Qbtech AB

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Contact person: Hans Boström

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Trade Name: QbTest

Classification name: Recorder, attention task performance

Product Code: LQD

Predicate Device: QbTest (K040894) and Gordon Diagnostic System (K854903)

Description	Gordon Diagnostic System (K854903)	QbTest (K040894)	QbTest v3.5
Intended use	The Gordon Diagnostic System (GDS) aids in the diagnosis of attention deficits, especially Attention Deficit Hyperactivity Disorder (ADHD). It provides reliable, objective information about an individual's	QbTest (K040894) provides clinicians with objective measurements of hyperactivity, impulsivity, and inattention to aid in the clinical assessment of ADHD. QbTest results should be interpreted only by qualified professionals.	QbTest v3.5 provides clinicians with objective measurements of hyperactivity, impulsivity, and inattention to aid in the clinical assessment of ADHD. QbTest results should be interpreted only by qualified professionals.

	ability to sustain attention and exert self-control.		

Device Description: QbTest is a non-invasive test that has been developed to provide precise quantitative assessment of the capacity for 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
- Responder button (also referred to as responder unit)
- Infrared camera
- Reflective motion marker
- User manual
- Technical manual
- Stimulus card
- Camera stand
- Measuring tape
- QbTest Behaviour Rating Scale

- In addition, the user must have access to a remote server that generates test reports

Indications for Use: QbTest is indicated to be used to aid in the clinical assessment of ADHD. QbTest results should be interpreted by qualified health care professionals only.

Intended use: QbTest provides clinicians with objective measurements of hyperactivity, impulsivity, and inattention to aid in the clinical assessment of ADHD. QbTest results should be interpreted only by qualified professionals.

Comparison of QbTest is substantially equivalent to the original QbTest

technological characteristics to predicate device:

(K040894).

It provides the same or similar functions and has a similar design. Both the current version of QbTest and the original version of QbTest (K040894) are indicated to aid in the assessment of ADHD. Both provide objective measurements of impulsivity, inattention and hyperactivity to aid in this process. Both are microprocessor-based vigilance task recorders with motion detection.

The current version of QbTest can also be used in adolescents and adults as Gordon Diagnostic System (K854903).

Performance Testing: The camera is tested in accordance with EN60825-1:1994. The System is tested in accordance with EN 60601-1 "Electrical Equipment, Part 1: General Safety Requirements" and EN 60601-1-2 "Electromedical equipment, EMC"

Clinical Testing: Normative tests have been gathered from several different cohorts resulting in a normative database of 1307 individuals between 6 and 60 years with an even age and gender distribution. The characteristics of this norm database and the methods to generate age and gender specific comparisons are described in the technical manual. There are four published studies which have evaluated the clinical validity of the QbTest for its intended use population. In addition, two test-retest studies have been completed to demonstrate the reliability of the QbTest.

Conclusions: QbTest v3.5 is substantially equivalent to the original QbTest (K040894). It provides the same or similar functions and has a similar design. Both the original QbTest (K040894) and QbTest v3.5 are indicated to aid in the assessment of ADHD. Both provide objective measurements of impulsivity, inattention and hyperactivity to aid in this process. Both are microprocessor-based vigilance task recorders with motion detection.

QbTest v3.5 can be used also in adolescents and adults as can the Gordon Diagnostic System (K854903).

The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs at least as safely and effectively as the legally marketed device identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 17 2012

Qbtech AB
% Mr. Hans Bostrom
Medical Director
Kungsgatan 29
11156 Stockholm
Sweden

Re: K122149
Trade/Device Name: QbTest v3.5
Regulation Number: Unclassified
Regulation Name: Recorder, Attention Task Performance
Regulatory Class: Class II
Product Code: LQD
Dated: July 17, 2012
Received: July 19, 2012

Dear Mr. Bostrom:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT FOR INDICATIONS FOR USE

510 (k) Number (if known): K122149

Device Name: QbTest

Indications for Use:

QbTest provides clinicians with objective measurements of hyperactivity, impulsivity, and inattention to aid in the clinical assessment of ADHD. QbTest results should be interpreted only by qualified professionals.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use (21 GFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K122149