510(k) Summary of safety and effectiveness

Date: March 24, 2014

510(k) Submitter:
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Trade Name: QbTest

Classification name: Recorder, attention task performance

Product Code: LQD

Predicate Device: QbTest (K122149)

Device Description: 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
- 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

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.

Comparison of technological characteristics to predicate device:

QbTest is substantially equivalent to QbTest (K122149).

It provides the same functions and has an identical design.

The current version of QbTest can also be used to aid qualified professionals in the evaluation of treatment interventions in patients with ADHD.

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 Performance Data:

The intended use of QbTest to support qualified professional in the evaluation of treatment interventions in ADHD is not based on one specific prospective study. Instead it is based on collated data from seven published clinical studies where QbTest has been used to evaluate different treatment interventions and one registry study, specifically designed to compare QbTest with clinically validated Rating Scales (RS) in the evaluation of treatment interventions.

Two of the published clinical studies evaluated the responsiveness of the test after single doses of central stimulants (CS) and two other studies focused on the capacity of the test to measure effects over the day for atomoxetine and CS (1-4).

Three of the published studies and the registry study evaluated the Effect Size (ES) of different treatment interventions measured by QbTest. Two of these studies included a placebo control group. In the first placebo-controlled study (5), with the objective to evaluate the effect of atomoxetine by means of QbTest and clinical rating scales, 128 children with ADHD (mean age 9.0) were randomized to treatment with atomoxetine or placebo and followed for 8 weeks. The per-protocol ES (Cohens *d;* small 0.2, moderate 0.5, and large 0.8) for the principal QbTest hyperactivity variables (Time active, Distance, Area and Microevents) varied between 0, 85 and 1, 49. The corresponding ES for the principle variables measuring inattention (Reaction Time Variation and Omission Errors) were 1.24 and 0.8 respectively and the principle variable measuring impulsivity (Commission Errors) showed an ES of 0,82. All changes from baseline were statistically significant. In the second placebo controlled study (6), 36 medication-naïve children aged 9 - 14 years diagnosed with ADHD were treated with methylphenidate, dexamphetamine and placebo for 3 weeks in a cross-over fashion. Group-level analyses revealed a statistically significant overall treatment effect for stimulant treatment compared to placebo with an ES of 0.62 measured by QbTest (partial eta-square; small 0.01, moderate 0.06 and large 0.14).

In a third study (7), QbTest was used to evaluate the effect of 16 and 52 weeks of treatment with methylphenidate in 23 adults. The ES (partial eta-square; small 0.01, moderate 0.06 and large 0.14) for the different QbTest hyperactivity variables (Time active, Distance, Area and Microevents) varied between 0.43 and 0.51. The ES for the variables measuring inattention (Reaction Time Variation and Omission Errors) was 0.51 and 0.46 respectively and the principle variable measuring impulsivity (Commission Errors) showed an ES of 0.28. Repeated measure ANOVAS showed statistically significant changes from baseline for all QbTest variables.

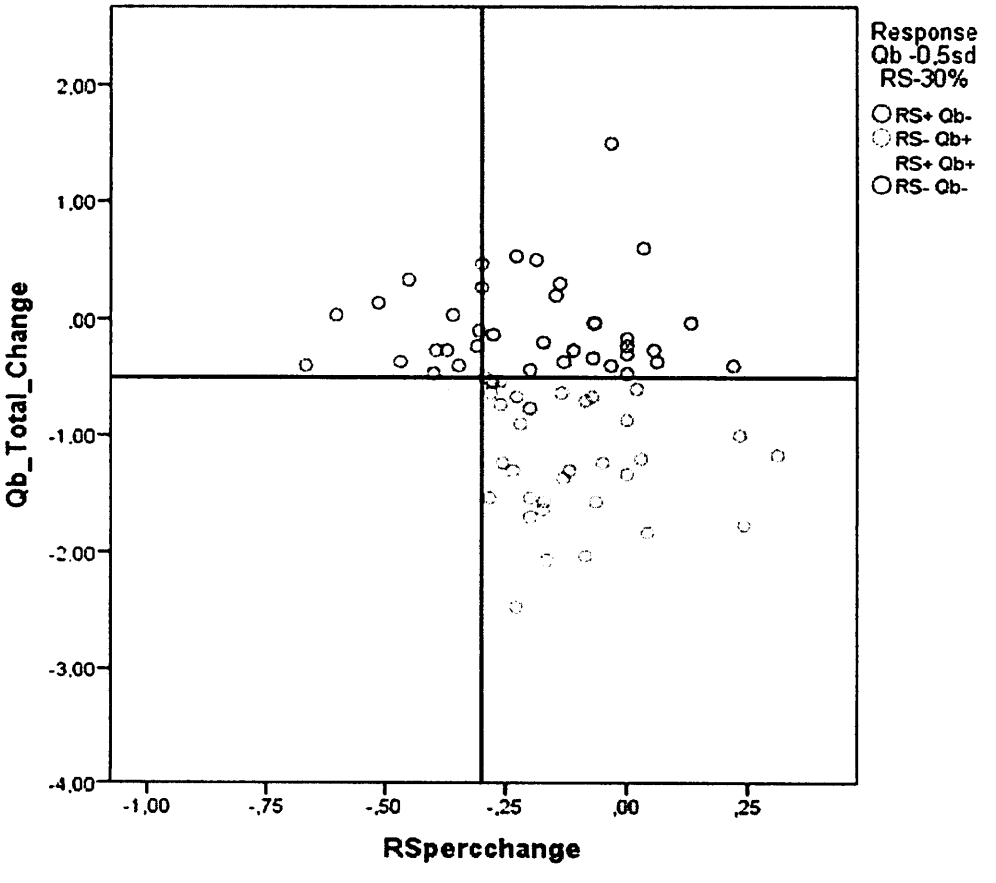
The registry study included consecutive patients, 42 children/adolescents (mean age 11.5) and 73 adults (mean age 35), with QbTest and clinical Rating Scale (RS) data at baseline and after treatment with central stimulants or atomoxetine. Time to follow up varied between 6 days and 10 weeks. The ES (Cohens *d;* small 0.2, moderate 0.5, and large 0.8) for the QbTest Total score (*QbActivity+ QbInattention + QbImpulsivity*)/3 and the RS Total score were 1.06 and 0.98 respectively. Changes from baseline were statistically significant for both methods. Time to follow up after treatment initiation was 5-6 weeks (10 weeks for atomoxetine treated patients) in the child/adolescent cohort and 6 to 65 days in the adult cohort. Of the 42 patients included from the child/adolescent cohort, 35 were male and 7 were female. The mean age was 11.5 years (8.5-15.7). Diagnosis was according the DSM-IV criteria and the baseline ADHD symptoms averaged 1.38 (SD = .36) on the ADHD items with a three step Likert scale ranging from "0- Does not apply" to "2-Definitely applies". This represents an at least moderately severity of ADHD. Of the 73 clinical patients included in the analysis from the adult cohort, 32 were women and 41 were men. The mean age was 35 years (18.6-54.1 years). Fifty-eight patients were diagnosed as ADHD combined subtype and 15 patients as ADHD inattentive subtype. The baseline ADHD symptoms in this cohort had an average of 1.95 (SD = .45) on a four step Likert scale ranging from "0- Never or seldom" to "3- Very often". This represents an at least moderately severity of ADHD. Data on ethnicity and social economic status was not collected in the two cohorts since this is not a routine at these clinical centres. The child cohort consisted of a sample of Swedish children assessed for ADHD and the adult cohort consisted of a sample of Dutch adults assessed for ADHD. It can thus be assumed that the majority of the included patients were Caucasians.

Subjects in each cohort		
Cohort	Frequency	Percent
Adult	73	63.5
Child	42	36.5
Total	115	100

Although the ES in the above studies all show large treatment effects they must be interpreted with caution since two of the studies did not include a concurrent control arm.

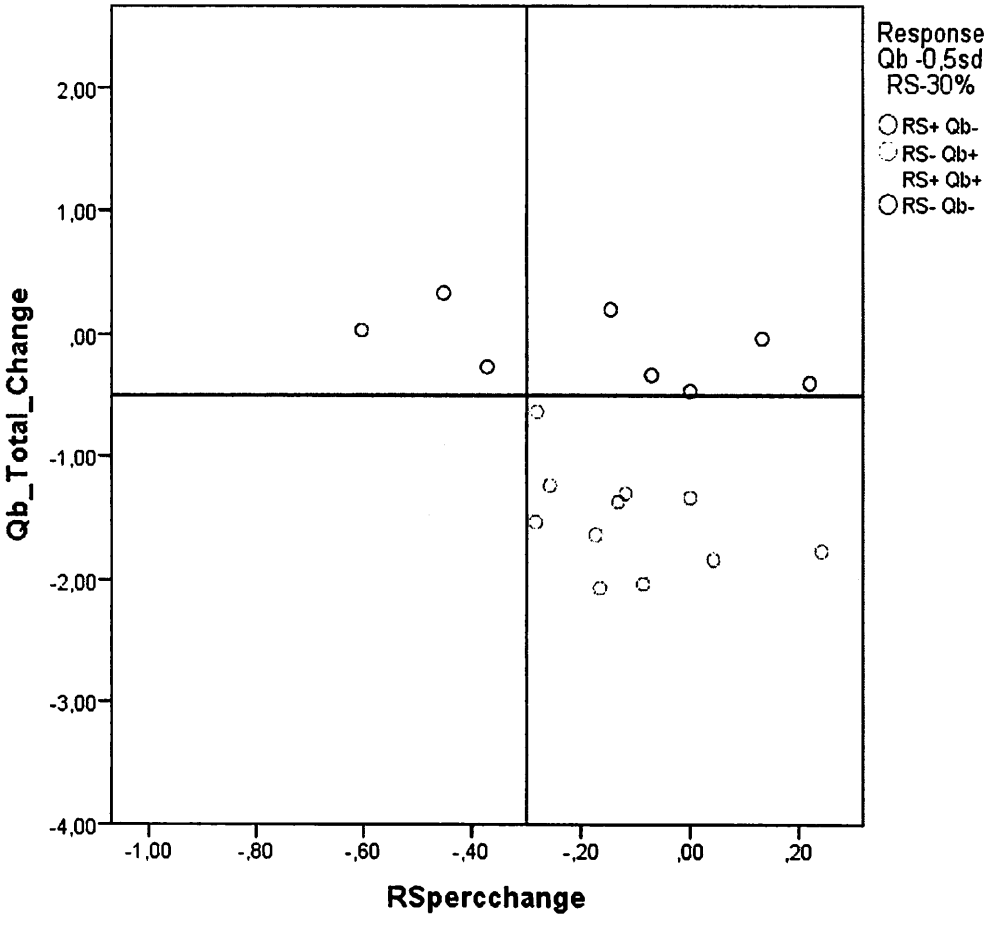
In addition to the comparison of ES between QbTest and RS, correlations between QbTest based treatment responses and RS based treatment responses were calculated in the registry study. In several studies where rating scales has been used to evaluate treatment effects, a change of -30% in ADHD RS Total score has been used as a threshold for a meaningful response to treatment. It should however be pointed out that this threshold has nothing to do with the imprecision of rating scales. Rather, this cut-off is based on clinical experience. The same logic can be used for QbTest. Although the imprecision of QbTest has been defined to 0.36 Q-scores, the Q-score of - 0.5 is used as a cut-off that defines a meaningful change from baseline. This cut off is based on clinical experience and psychometric conventions. Consequently, the above clinically based thresholds for a meaningful treatment effect were utilized when the correlation between QbTest and RS was evaluated. The figures and tables below show individual treatment responses, calculated response rates as well as Negative Percent Agreement (NPA) and Positive Percent Agreement (PPA) with Confidence Intervals (CI) for the two methods.

Pooled Cohort Analysis:



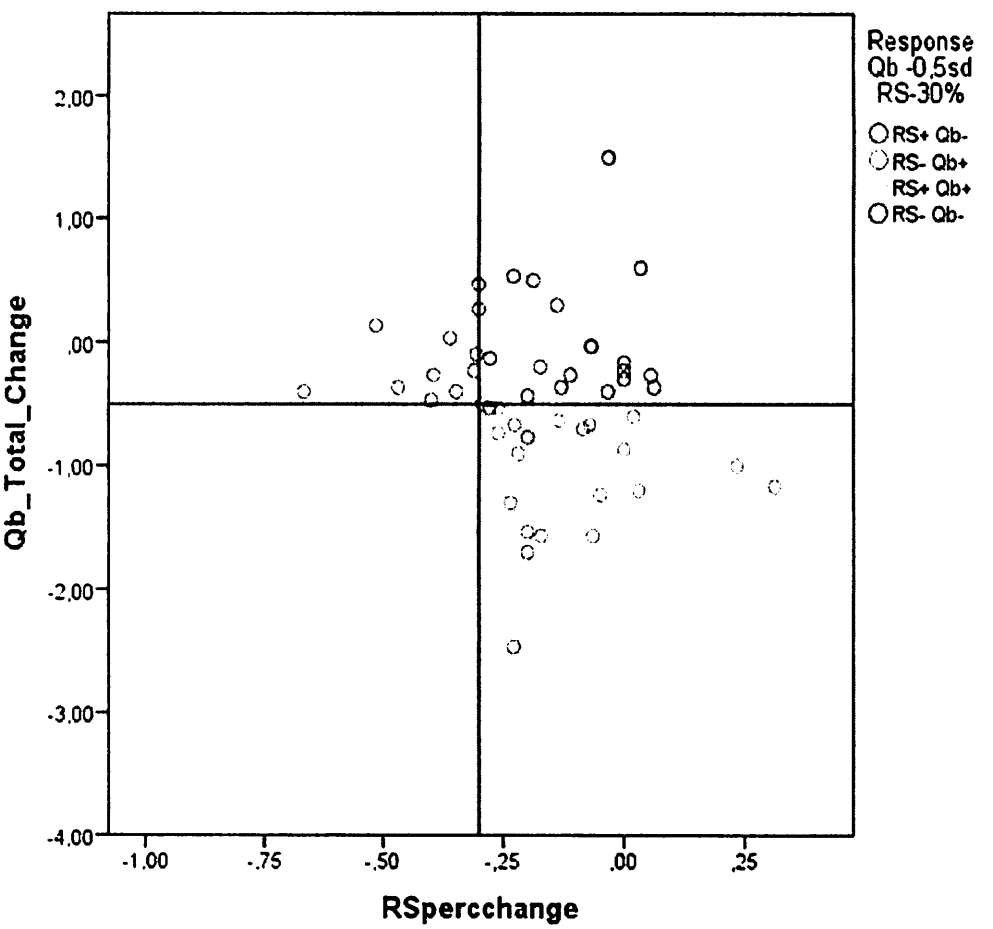
		RS Total Score		
	Pooled Cohort	No Improvement	Improvement	Total
QbTest Total Score	No Improvement	23	14	37
	Improvement	35	43	78
	Total	58	57	115
NPA = 40 (23/58) CI: 28 to 53 PPA = 75 (43/57) CI:63 to 85				

Child Cohort Analysis:



		RS Total Score		
	Child Cohort	No Improvement	Improvement	Total
QbTest Total Score	No Improvement	5	3	8
	Improvement	11	23	34
	Total	16	26	42
NPA = 31 (5/16) CI: 14 to 56 PPA = 88 (23/26) CI: 71 to 96				

Adult Cohort Analysis:



		RS Total Score		
	Adult Cohort	No Improvement	Improvement	Total
QbTest Total Score	No Improvement	18	11	37
	Improvement	24	20	44
	Total	42	31	73
NPA = 43 (18/42) CI: 29 to 58 PPA = 65 (20/31) CI: 47 to 79				

The registry study showed statistically significant but low correlations between QbTest and the clinically validated rating scales (RS). Therefore and in the absence of a well-defined gold standard for the evaluation of treatment effects in ADHD, QbTest results should be complemented by a clinical evaluation of the treatment effects to avoid the risk that QbTest results should indicate that a treatment is ineffective when it is clinically effective and that QbTest results should indicate that a treatment is effective when it is clinically ineffective.

References:

1. Vogt, C., & Williams, T. (2011). Early identification of stimulant treatment responders, partial responders and non-responders using objective measures in children and adolescents with hyperkinetic disorder. *Child and Adolescent Mental Health, 16,* 144-149.
2. Edebol, H., Helldin, L., Norlander, T. (2013). The Weighed Symptom Scale and Prediction of ADHD in Adults- Objective Measures of Remission and Response to Treatment with Methylphenidate. *Clinical Practice & Epidemiology in Mental Health, 9*, 171-179.
3. Wehmeier, P.M., Schacht, A., Wolff, C., Otto, W.R., Dittman, R.W., & Banaschewski, T. (2011). Neuropsychological outcomes across the day in children with attention-deficit/hyperactivity disorder treated with atomoxetine: Results from a placebo-controlled study using a computer-based continuous performance test combined with an infra-red motion-tracking device. *Journal of Child and Adolescent Psychopharmacology, 21*, 430-444.
4. Günther, T., Kahraman-Lanzerath, B., Knospe, E.L., Herpertz-Dahlmann, B. & Konrad, K. (2012). Modulation of attention-deficit/hyperactivity disorder symptoms by short- and long-acting methylphenidate over the course of a day. *Journal of Child and Adolescent Psychopharmacology, 22*, 1-8.
5. Wehmeier, P.M., Schacht, A., Ulberstad, F., Lehmann, M., Schneider-Fresenius, C., Lehmkuhl, G., Dittman, R.W., & Banaschewski, T. (2012). Does atomoxetine improve executive function, inhibitory control, and hyperactivity? Results from a placebo-

controlled trial using quantitative measurement technology. *Journal of Clinical Psychopharmacology, 32*, 653-660.
6. Ramtvedt, B.E., Røinås, E., Aabech, H.S. & Sundet, K.S. (2013). Clinical gains from including both dextroamphetamine and methylphenidate in stimulant trials. *Journal of Child and Adolescent Psychopharmacology, 23*, 1-8.
7. Ginsberg, Y., Hirvikoski, T. & Grann, M. (2012). Long-term functional outcome in adult prison inmates with ADHD receiving OROS-methylphenidate. *European Archives of Psychiatry and Clinical Neuroscience, 262*, 705-724.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 24, 2014

QbTech AB
c/o Hans Boström, MSc., PhD.
Medical Director
Kungsgatan 29, 7tr
S-111 56 Stockholm
Sweden

Re: K133382
Trade/Device Name: QbTest
Regulation Number: Unclassified
Device Classification Name: recorder, attention task performance
Regulatory Class: Unclassified
Product Code: LQD
Dated: March 24, 2014
Received: March 24, 2014

Dear Dr. Boström:

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 contact 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. 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,

Carlos L. Pena -S

Carlos L. Peña, Ph.D., M.S.
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K133382

Device Name

QbTest

Indications for Use *(Describe)*

QbTest provides clinicians with objective measurements of hyperactivity, impulsivity, and inattention to aid in the clinical assessment of ADHD (Attention Deficit Hyperactivity Disorder) and in the evaluation of treatment interventions in patients with ADHD. QbTest results should be interpreted only 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos L. Pena -S

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

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