



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 22, 2016

QbTech AB
Hans Boström, MSc., PhD.
Medical Director
Kungsgatan 29
Stockholm, Sweden 11156

Re: K143468

Trade/Device Name: QbCheck
Regulation Number: Unclassified
Device Classification Name: Recorder, Attention Task Performance
Regulatory Class: Unclassified
Product Code: LQD
Dated: March 14, 2016
Received: March 15, 2016

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

**William J.
Heetderks -A**

Digitally signed by William J. Heetderks -A
DN: c=US, o=U.S. Government, ou=HHS,
ou=NIH, ou=People,
0.9.2342.19200300.100.1.1=0010149848,
cn=William J. Heetderks -A
Date: 2016.03.22 20:49:21 -04'00'

for

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

Indications for Use

510(k) Number (if known)

K143468

Device Name

QbCheck

Indications for Use (Describe)

QbCheck provides health care professionals 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. QbCheck results should be interpreted only by qualified health care 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 of Safety and Effectiveness

Date: December 3, 2014

510(k) Submitter: Qbtech AB
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Contact person: Hans Boström
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Trade Name: QbCheck

Classification name: Recorder, attention task performance

Product Code: LQD

Predicate Device: QbTest (K133382)

Device Description: QbCheck 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. QbCheck 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 QbCheck is a computer-assisted attention and impulse control task and simultaneous recording of activity.

QbCheck is an online solution and no extra hardware is needed as the test is performed on the user's own computer. For the activity tracking analysis QbCheck uses the built in camera in the user's laptop or a separate web camera on the user's desktop computer.

QbCheck consists of the following;

- QbCheck client and server software

510k application – QbCheck

- Online test with instructions, a continuous performance task (CPT) and motion measurement technology through web camera.
- Access to a remote server which generates test results
- Secure access to a result report
- User manual
- Technical manual
- QbCheck Behavior Observation Form

Intended use:

QbCheck provides healthcare professionals 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. QbCheck results should be interpreted only by qualified healthcare professionals.

Comparison of technological characteristics to predicate device:

QbCheck is substantially equivalent to QbTest (K133382).

It provides the same functions and the test has an identical design. Instead of a responder button, the test-taker uses the spacebar to respond to targets and instead of an infrared camera and a reflective motion marker, the test-takers motor activity during the test is registered by the web camera.