K040894

JUN 2 2 2004

510(k) Summary of safety and effectiveness

Date: 03/26/2004

510(k) Submitter:
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Contact person: Maria Berglund
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Trade Name: QbTest

Classification name: Recorder, attention task performance

Product Code: LQD

Predicate Device: OPTAx System (K020800)

Device Description: The QbTest is a 15 minute, non invasive test that has been developed to provide precise quantitative assessment of the capacity of children to pay attention to visual stimuli while inhibiting their loco motor activity and controlling their urge to respond impulsively. There are three cardinal disturbances in Attention-Deficit Hyperactivity Disorder (ADHD) impaired attention, hyperactivity and impulsivity. QbTest provides an accurate and reproducible measure of a child'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-administered go/not-go vigilance response task combined with motion capture.

The system consists of the following components;

- Client PC software
- Connection box
- Responder button
- Camera for motion measurement
- Reflective marker
- USB and serial cable

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 technological characteristics to predicate device: QbTest is substantially equivalent to the OPTAx system (K020800). It provides the same or similar functions and has a similar design. The new characteristics do not affect safety or effectiveness. Both the OPTAx system and QbTest 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.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Maria Berglund
Quality Assurance
QbTech AB
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417 64 Göteborg
Sweden

Re: K040894
Trade/Device Name: QbTest
Regulatory Class: Unclassified
Product Code: LQD
Dated: March 26, 2004
Received: April 29, 2004

Dear Ms. Berglund:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040894

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____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040894