JUN 1 0 2002

K020800

OPTAx Systems Inc.
510K Summary of Safety and Effectiveness
June 6, 2002

1. Sponsor Name

OPTAx Systems Inc.
20 Mall Rd. Suite 210
Burlington, MA 01803

2. Device Name

Proprietary Name: OPTAx System
Common/Usual Name: RECORDER, ATTENTION TASK PERFORMANCE

3. Identification of Predicate or Legally Marketed Device

Gordon Diagnostic System cleared under K854903.

4. Device Description

OPTAx (Optical Tracking and Attention test) is a 15 minutenon-invasive, office-based test that was developed to provide precise quantitative assessment of the capacity of children to pay attention to visual stimuli, while inhibiting their locomotor activity and controlling their impulsive responses. The three core symptoms of Attention-Deficit Hyperactivity Disorder (ADHD) are : impaired inattention, hyperactivity, and impulsivity. OPTAx 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 OPTAx is a computer-administered GO/NO-GO vigilance response task.

The OPTAx System consists of the following components:

- IMac computer and peripherals (printer and adapters)
- Pre-installed OPTAx software program
- Motion analysis camera and peripherals
- Data analysis software on the OPTAx secure server

5. Intended Use

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

6. Comparison of Technological Characteristics

Both the Gordon and OPTAx Systems are indicated to aid in the diagnosis and assessment of ADHD. Both provide objective measurements of impulsivity and inattention to aid in this process; OPTAx also provides objective measurements of hyperactivity.

Both are microprocessor-based vigilance task recorders.

7 Performance Testing

Bench testing of the camera to EN 60825-1-1994, safety standards has been performed. Clinical testing has also been performed on the OPTAx System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 0 2002

OPTAx Systems, INC.
c/o Ms. Debbie Iampietro
QRC Consulting
7 Tiffany Trail
Hopkinton, MA 01748

Re: K020800
Trade/Device Name: OPTAx System
Regulatory Class: Unclassified
Product Code: LQD
Dated: March 8, 2002
Received: March 12, 2002

Dear Ms. Iampietro:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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

510(k) Number (if known): K020800

Device Name: OPTAx System

Indications For Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

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

510(k) Number K020800