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

October 15, 2014

AnthroTronix, Inc.
Dr. Corinna Lathan
Chief Executive Officer
8737 Colesville Road, Suite L-203
Silver Spring, MD 20910

Re: K141865
Trade/Device Name: DANA
Regulation Number: Unclassified
Device Classification Name: Recorder, Attention Task Performance
Regulatory Class: Unclassified
Product Code: LQD
Dated: July 9, 2014
Received: July 10, 2014

Dear Dr. Lathan:

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 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,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
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 below.

510(k) Number *(if known)*
K141865

Device Name
DANA

Indications for Use *(Describe)*
DANA provides clinicians with objective measurements of reaction time (speed and accuracy) to aid in the assessment of an individual's medical or psychological state. Factors that may affect the measurement of reaction time include, but are not limited to concussion, head injury, insomnia, post traumatic stress disorder (PTSD), depression, attention deficit hyperactivity disorder (ADHD), memory impairment, dementia, delirium, prescription and non-prescription medication, some nutritional supplements, as well as a variety of psychological states (e.g. fatigue and stress).

DANA also delivers and scores standardized psychological questionnaires. DANA 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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1.0 510(K) SUMMARY

Submission Date: September 18, 2014

Submitter Information:

Company: AnthroTronix, Inc.
8737 Colesville Road, Suite L203
Silver Spring, MD 20910

Contract Person: Corinna E. Lathan, PhD, PE
CEO
AnthroTronix, Inc.
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Device Information:

Trade Name: DANA

Common Name: Mobile Based Task Performance Recorder

Classification Name: Recorder, Attention Task Performance

Device Class: Unclassified

Predicate Device: QbTest (K122149)
Qbtech AB
Unclassified

Device Description:

DANA is a mobile application indicated to provide clinicians with objective measurements of reaction time (speed and accuracy) and standardized health assessments to aid in the assessment of an individual's medical or psychological state. DANA results should be interpreted only by qualified professionals.

DANA was developed on a mobile platform to improve the access and availability of reaction time tests and standardized health assessments through (1) custom configuration of the system by clinicians based on their need and discretion; and (2) allowing for objective health assessments both in-clinic and out-of-clinic settings.

Indications for Use:

DANA provides clinicians with objective measurements of reaction time (speed and accuracy) to aid in the assessment of an individual's medical or psychological state. Factors that may affect the measurement of reaction time include, but are not limited to concussion, head injury, insomnia, post traumatic stress disorder (PTSD), depression, attention deficit hyperactivity disorder (ADHD), memory impairment, dementia, delirium, prescription and non-prescription medication, some nutritional supplements, as well as a variety of psychological states (e.g. fatigue and stress).

DANA also delivers and scores standardized psychological questionnaires. DANA results should be interpreted only by qualified professionals.

Comparison to Predicate Device:

DANA is substantially equivalent to QbTest (manufactured by Qbtech AB; K122149). DANA and the QbTest share the same intended use as Attention Task Performance Recorders. DANA and the QbTest are similar in terms of technological characteristics as both electronically record objective performance measurements (speed and accuracy) as the patient responds to stimuli presented on the screen by either clicking a button or touching the screen. The QbTest differs from DANA in that a computer is used to administer the test, as compared to DANA, which uses a mobile device. The QbTest also differs in technology from DANA in that the QbTest includes an infrared camera to monitor patient movement, which factors into the performance measurements. DANA does not include an infrared camera to monitor patient movement, and therefore does not use physical activity in providing performance measurements. Differences in the design and performance of DANA from the QbTest do not affect either the safety or effectiveness of DANA for its intended use.

Supporting Information:

Software testing was conducted in accordance with FDA's May 2005 guidance document entitled, "Guidance for Industry and FDA Staff. Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Conclusion:

DANA falls within the generic type of device regulated by the LQD Product Code (Recorder, Attention Task Performance). Differences in the design and performance of DANA from the QbTest do not affect either the safety or effectiveness of DANA for its intended use. Therefore, DANA is substantially equivalent to the QbTest.