K063872

510(k) SUMMARY

APR - 6 2007

The Summary of Safety and Effectiveness information on Kinesia™ is being submitted in accordance with the requirements of 21 C.F.R. §807.92 and reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

Applicant	Cleveland Medical Devices Inc. 4415 Euclid Avenue Cleveland, Ohio 44103
Telephone **Facsimile**	(216) 791-6720 (216) 791-6739
Date	April 5, 2007
Name	Hani Kayyali, President
Classification	882.1400
Predicate:	Family of Crystal 20 Monitors, K042039, Tremorometer, K010270, and Actiwatch-Score, K991033.
Description:	Kinesia™ is designed to monitor and record motion and electrical activity of muscle to quantify kinematics of movement disorders such as tremor for research and diagnostic purposes. The patient unit consists of a wrist module and ring sensor. Motion sensors including accelerometers and gyroscopes are integrated into a finger worn unit to capture three dimensional motions. The finger worn sensor unit is worn on a finger band and is connected to a wrist worn module by a thin flexible wire. The wrist module provides an input for two channels of electromyography, battery power, on board memory, and an embedded radio for real-time wireless transmission of the collected signals. The wrist module is worn on a comfortable, adjustable wristband. The signals are communicated between the patient module and the computer unit using wireless technology based on 2.4–2.484 GHZ frequencies. Kinesia will consist of four major components: *1. Patient Module(consists of ring and wrist module)* *2. Computer Unit* *3. Electromyography Leads* *4. Interface Software* 1. The ***Patient Module*** includes a user worn ring and wrist module connected by a thin cable. The patient module monitors eight channels of data including three channels of accelerometers (linear acceleration sensors), three channels of gyroscopes (angular velocity sensors), and two channels of electrical muscle activity (EMG). The data can be transmitted in real-time over a wireless telemetry link to a computer or be stored in onboard memory. The wireless link can either transmit only (one-way) or transmit and receive (two-way). The basic functional feature of the component is to acquire signals from the subject, perform analog-to-

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Description	digital conversion (when appropriate), encode, format, and transmit the signals to the Computer Unit or store data in on board memory. The Patient Module will operate on DC power from either rechargeable or replaceable batteries. The Patient Module includes a push button patient diary so the patient can indicate when they have taken their medication and when their symptoms are severe. 2. The ***Computer Unit*** will have the ability to only receive (one-way) or receive and transmit (two-way) data from the Patient Module. The basic functional feature of this component is to receive data packets from the patient unit, perform error detection and correction, and then send the data to the PC Operator interface where the data can be monitored in real time or stored and analyzed at a later time. 3. The Electromyography Leads provide an input for two channels of EMG recordings. The leads provide five standard snap connector inputs including two differential channels of EMG and a patient ground. The leads are connected to a lemo connector. The lemo connector attaches to the lemo input on the Patient Unit wrist module. 4. The ***Interface Software*** program consists of several software modules that allow the user to acquire, store, and review data as acquired by the hardware.
Intended Use	Kinesia is intended to monitor physical motion and muscle activity to quantify kinematics of movement disorder symptoms such as tremor and assess activity in any instance where quantifiable analysis of motion and muscle activity is desired.
Contraindication:	Interference may occur in the vicinity of equipment marked with the following symbol:  Such interference could be caused by the use of multiple units operating in the same vicinity.
Warning	• Improper routing of leads may result in a choking hazard. • Do not use in conjunction with a defibrillator. • Do NOT expose the system to water. Water exposure may permanently damage the unit.
Technological Characteristics	Like the predicate devices, Kinesia is intended to monitor and record motion and physiological signals from a patient's body, and save those signals for analysis and review.

510(k) SUMMARY, continued

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Performance Testing	Kinesia™ will be tested to the following voluntary standards: • FCC Part 15.109 Radiated emissions limits – Unintentional radiators. Class B digital device. • IEC60601-1, 10.1 Environmental Conditions, Transport and Storage • IEC60601-1, 10.2 Environmental Conditions, Operation • IEC60601-1, 19.3 Leakage currents, allowable values • IEC60601-1-2, 36.202.3 Radiated RF electromagnetic fields • IEC60601-1-2, 36.202.4 Electrical fast transient and bursts • IEC60601-1-2, 36.202.7 Voltage dips, short interruptions, and voltage variations • IEC60601-1-2, 36.202.6 Conducted Disturbances, Induced by RF fields • IEC60601-1-2, 36.202.8 Magnetic Fields • IEC60601-1-2, 36.202.2 Electrostatic Discharge • IEC60601-1-2, 36.201 Emissions
Conclusion	It is the conclusion of Cleveland Medical Devices Inc. that Kinesia is substantially equivalent to the predicate devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Cleveland Medical Devices Inc.
c/o Mr. Joseph Giuffrida
Director, Division of Movement
4415 Euclid Ave.
Cleveland, OH 44103

APR - 9 2012

Re: K063872
Trade/Device Name: Kinesia
Regulation Number: 21 CFR 882.1950
Regulation Name: Tremor Transducer
Regulatory Class: II
Product Code: GYD
Dated (Date on orig SE ltr): April 5, 2007
Received (Date on orig SE ltr): April 5, 2007

Dear Mr. Giuffrida:

This letter corrects our substantially equivalent letter of April 6, 2007.

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 (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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063872

Device Name: Kinesia

Indications For Use:

Kinesia is intended to monitor physical motions and muscle activity to quantify kinematics of movement disorder symptoms such as tremor and assess activity in any instance where quantifiable analysis of motion and muscle activity is desired.

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)

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

510(k) Number K063872