DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 5, 2016

BioGaming Ltd.
c/o Suzan Onel, Partner and Chair, Global FDA Practice
K&L Gates LLP&K
1601 K Street, NW
Washington, DC 20006

Re: K151955
Trade/Device Name: YuGo System
Regulatory Class: Unclassified
Product Code: LXJ
Dated: December 31, 2015
Received: January 5, 2016

Dear Suzan Onel:

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,

Michael J. Hoffmann -A

for Carlos 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)*
K151955

Device Name
YuGo system

Indications for Use *(Describe)*
A software system used with the Microsoft Kinect intended to be used to support the physical rehabilitation of adults in the clinic/ at home. The system includes rehabilitation exercises for the lower and upper extremities with audio- visual feedback & graphic movement representations for patients as well as remotely accessible patient performance metrics for the medical professional. Patient assessment, exercise guidance and approval by the medical professional is required prior to use.

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

510(K) Number K151955

5.1 Applicant's Name:

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5.2 Contact Person:

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5.3 Date Prepared: December 31, 2015

5.4 Trade Name: YuGo System

5.5 Common or Usual Name: Software system utilizing optical position recording for rehabilitation exercises

5.6 Classification Name: System, optical position/movement recording

5.7 Device Panel: Physical Medicine

5.8 Product Code: LXJ

5.9 Classification Regulation: None. Reason: YuGo is substantially equivalent to predicates in product code LXJ. The product code is 'unclassified' in FDA's product classification database with the reason being 'pre-amendment'. Refer to URL: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?ID=4850

5.10 Predicate Device:

Jintronix Rehabilitation System (“JRS”) (Jintronix Inc.), cleared under K130847; product code: LXJ (System, Optical Position/Movement Recording).

5.11 Intended Use / Indication for Use:

A software system used with the Microsoft Kinect intended to be used to support the physical rehabilitation of adults in the clinic/ at home. The system includes rehabilitation exercises for the lower and upper extremities with audio-visual feedback & graphic movement representations for patients as well as remotely accessible patient performance metrics for the medical professional. Patient assessment, exercise guidance and approval by the medical professional is required prior to use.

5.12 Device Description:

The YuGO device, developed by Biogaming Ltd. is a virtual reality platform used with the Microsoft Kinect motion sensing technology, which provides exercise programs for the body’s lower and upper extremities. It allows physical therapists to define professional, supervised, and personalized exercise programs via video games or a virtual trainer.

The system was designed to serve a number of purposes:

a) Allowing the treating clinician a direct access to the training program performed at the patients' home, by determining the allowed movements, extent and difficulty levels of the training protocol.

b) Encourage physical therapy home-training through the use of camera-sensors, visualizing and promoting body movements using a game displayed on screen.

c) Collecting movement and performance related data from the home-user; analyzing it and instantly preparing a report on a designated website, to allow treating clinicians (the patients’ Physical Therapist or a Physician) access to a "performance report", in order to monitor, adjust and otherwise modify the training protocol to suit the needs of the patient in his rehabilitation process.

The system includes three (3) main functions: Clinician Dashboard, Patient Interface and Reporting System. Using the Microsoft Kinect for Windows to track motion, the YuGo Patient Interface records performance metrics providing them to qualified medical professionals via the Clinician Dashboard, in the Reporting system. Medical professionals can monitor patients performance, assign or modify rehabilitation exercises in Patient Interface for their patients through the Clinician Dashboard allowing for patients to perform their prescribed rehabilitation program even from the comfort of their home.

5.13 Substantial Equivalence:

Intended Use and Indications for Use

The subject YuGo System and predicate Jintronix Rehabilitation System (JRS) have the same intended use and identical indications for use, except for the fact that the JRS is intended for the upper extremity and trunk only and the YuGo is also intended for the lower extremities, but not for the trunk. The additional lower extremity exercises available with the YuGo system do not present additional safety concern to the device, and do not change the substantial equivalence determination.

Comparison of Technological Characteristics

The YuGo system, like its predicate, is software used with the Microsoft Kinect intended to be used to support the physical rehabilitation of adults in the clinic/ at home, and require an internet connection to operate. The YuGo and JRS are based on a 3D sensor that analyses the patient's movements in real time and provides feedback on performance quality, guidance for improving performance and exercise results summary. The exercise is recorded and analyzed by the system for further monitoring by the therapist.

The following technological differences exist between the subject and predicate devices:

- YuGo clinician selects exercises and the software incorporates them into the patient interface (virtual trainer and games), while in the JRS system clinician is required to select the specific games (activities) based on his familiarity with them as suitable for the patient. This difference is a technological software progress and does not have any clinical affect, and therefore no new questions of safety and effectiveness are raised.
- The two products differ in the games currently included in them. These games serve only as a virtual environment for performing the prescribed rehabilitation exercises, and therefore this difference does not raise new questions of safety and effectiveness.
- Slightly lower minimal PC system requirements (such as Windows version, processor, memory, Kinect version, resolution) of the YuGo system. These minor differences have no clinical effects and therefore do not raise any new questions of safety and effectiveness.

Performance Testing

Software validation testing was conducted to verify that the device performs according to its specifications as described in the Software Requirements Specifications (SRS). The Software Test Description (STD) for the YuGo system presents the methodology for the validation and describes the test cases along with their acceptance criteria and the detailed test procedure. The

STD also includes the test log (including individual grade of Pass/Fail). The SRS and STD demonstrate that the YuGo system performs according to its specifications.

Summary

The YuGo and predicate device are software systems that share in common intended use/indications for use, target populations, anatomical sites, location of use and technological characteristics like principle of operation, design and technology used. The devices are intended for the physical rehabilitation of patients with orthopedic and neurological conditions. The two systems track limb and body motion while providing visual feedback. They are prescription use devices that enable home based rehabilitation exercises with remote medical professional control. The YuGo and equivalent predicate device make use of optical motion sensing technology and a computer operating system. YuGo and JRS also neither deliver energy to patients nor pose any issues in terms of electrical, chemical, mechanical, thermal, radiation safety or compatibility. YuGo is validated for system compatibility and performance. Therefore, BioGaming Ltd believes that the YuGo is substantially equivalent to its predicate.