DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 28, 2017

Barron Associates, Inc.
Bruce G. Wilson
Business Manager
1410 Sachem Place, Suite 202
Charlottesville, Virginia 22901

Re: K163245
Trade/Device Name: Virtual Occupational Therapy Application (VOTA)
Regulation Number: Unclassified
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: LXJ
Dated: February 1, 2017
Received: February 2, 2017

Dear Mr. Wilson:

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" (21 CFR 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,

Michael J. Hoffmann -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)*
K163245

Device Name

Virtual Occupational Therapy Application (VOTA)

Indications for Use *(Describe)*

A software system used with the Microsoft Kinect intended to be used to support repetitive task practice for rehabilitation of adults under supervision of a medical professional in a clinical or home setting. The system includes simulated activities of daily living (ADLs) for the upper extremity with audio-visual feedback & graphic movement representations for patients as well as 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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BARRON ASSOCIATES

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510(k) SUMMARY

5.1 Submitting Organization and Owner

Name: Barron Associates, Inc.
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Regulatory Contact: Bruce Wilson, Business Manager
Email: wilson@barron-associates.com
Date of preparation: 16 November 2016

5.2 Device

Trade Name	Virtual Occupational Therapy Application (VOTA)
Model Number	VOTA-1.0
Common Name	Software system utilizing optical position recording for supporting repetitive task practice for rehabilitation
Classification Name	System, Optical Position/Movement Recording
Review Panel	Physical Medicine
Product Code	LXJ
Device Class	Unclassified. VOTA is substantially equivalent to the predicate in Product Code LXJ. The Product Code is identified as "Unclassified" in the FDA database. Reason given is "Pre-Amendment." This information can be found at the flowing link: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=LXJ

5.3 Predicate Device

Predicate Trade Name	Jintronix Rehabilitation System (JRS)
Model Number	Version 1.0
510(k) Number	K130847
510(k) Holder	Jintronix, Inc.
Device	System, Optical Position/Movement Recording

Review Panel	Physical Medicine
Product Code	LXJ
Device Class	Product Code LXJ is Unclassified. Reason given is "Pre-Amendment."

5.4 Device Description

The VOTA software system comprises a VOTA patient-facing application and a provider-facing Provider Dashboard. The VOTA patient-facing application supports repetitive task practice exercises for the upper extremity that are consistent with Standard of Care for physical rehabilitation of adults. The software runs on a personal computer under the Windows 8.1 operating system (or later) and uses a Microsoft Xbox One Kinect Sensor (hereafter referred to as Kinect Sensor) to track patient arm movements. These arm movements are translated into equivalent movements of a graphical avatar that represents the patient in a virtual environment. The patient is thus able to practice activities of daily living (ADLs) that involve meaningful tasks and evoke functional movements with graduated levels of difficulty. The activities are organized into a virtual "Road to Recovery" that traverses a series of four islands, each organized around a central theme. There is no physical contact between the patient and the device during exercises, and thus no energy is directed to the patient. Patient assessment by a medical professional, and selection of exercise and settings, is required prior to use.

The provider-facing VOTA Provider Dashboard application enables the medical professional to view patient performance metrics and participation history using data produced by the VOTA patient-facing application. The application runs on the same personal computer and operating system as the patient-facing application.

All hardware associated with VOTA are commercial-of-the-shelf, consumer hardware items. The VOTA system ships with the following:

- Microsoft Xbox One Kinect Sensor and Kinect power supply;
- Microsoft Xbox Kinect Adapter for Xbox One ;
- Kinect TV Mount for Xbox One;
- Personal computer (preloaded with VOTA software) and computer power supply;
- Wireless keyboard;
- HDMI cable;
- Getting Started Guide; and
- Third-party Labeling Package

5.5 VOTA Indications for Use Statement

A software system used with the Microsoft Kinetic intended to be used to support repetitive task practice for rehabilitation of adults under supervision of a medical professional in a clinical or home setting. The system includes simulated activities of daily living (ADLs) for the upper extremity with audiovisual feedback & graphic movement representations for patients as well as patient performance metrics for the medical professional. Patient assessment, exercise guidance and approval by the medical professional is required prior to use.

5.6 Substantial Equivalence with Predicate - Intended Use

The VOTA Indications for Use Statement is highly similar to that of the Jintronix Rehabilitation System (JRS) (hereafter referred to as "the Predicate"). The following is the Predicate's Indications for Use Statement with a strikethrough line showing the words eliminated, and underlined text is used to show words added to form the VOTA Indications for Use Statement.

> *A software system used with the Microsoft Kinect intended to be used to support ~~the physical rehabilitation of adults in the clinic/ at home~~ repetitive task practice for rehabilitation of adults under supervision of a medical professional in a clinical or home setting. The system includes ~~rehabilitation exercises~~ simulated activities of daily living (ADLs) for the upper extremity ~~and trunk~~ 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.*

Differences in Indications for Use Statements		Why differences do not affect safety and effectiveness of VOTA when used as labeled.
VOTA	Predicate(s)	
repetitive task practice for rehabilitation of adults under supervision of a medical professional in a clinical or home setting	the physical rehabilitation of adults in the clinic/ at home	Repetitive task practice is a more precise definition of the element of standard of care implemented by VOTA. The clear statement that VOTA will be used under supervision reduces the VOTA risk profile compared to the Predicate.
simulated activities of daily living (ADLs)	rehabilitation exercises	Simulated ADLs is a more precise definition of the way the VOTA system supports rehabilitation. Simulated ADLs are highly consistent with standard of care and at least as safe as the Predicate's more generic rehabilitation exercises.
Does not include "and trunk"	Includes "and trunk"	Does not adversely affect the safety or effectiveness of the device
Does not include "remotely accessible" patient performance metrics	Includes "remotely accessible" patient performance metrics	Does not adversely affect the safety or effectiveness of the device

5.7 Technological Characteristics

VOTA device and the predicate have very similar technical characteristics. Both are software-based devices intended for the Windows operating system on a personal computer, and both use a Microsoft Kinect sensor for tracking patient upper extremity movements. Both translate movements to moving

images on the display, along with audio-visual feedback. Both systems provide performance metrics for the medical professional. Both systems are non-invasive, do not contact the patient, and do not direct energy toward the patient. Both systems are non-sterile in their requirements. Neither system poses concerns over electrical, chemical, mechanical, thermal or radiation safety. The following chart provides a substantial equivalence comparison.

Area of Comparison	Predicate	Applicant Device	Discussion
Principles of Operation	This system allows a medical professional to assign movement activities to patients. It tracks patient movement providing visual feedback and reports on kinematic parameters like velocity and joint angular changes during movement.	Same	No difference between VOTA and predicate.
Energy Used and/or delivered	As a software system, energy usage is low, and no energy is directed into patient.	As a software system, energy usage is low, and no energy is directed into patient.	No difference between VOTA and predicate.
Design	Per its 510(k) Summary, the Predicate system requires optical motion sensing technology and computer operating system with Windows for operation.	VOTA is a software system using Microsoft Kinect optical position sensor and a Windows personal computer operating system platform.	VOTA and the predicate employ substantially the same design considerations.
Materials / Technology used	The Predicate in its 510(k) Summary identifies two software modules, a Microsoft Kinect optical motion capture component and a Microsoft Windows computer workstation.	VOTA is a software system using Microsoft Kinect optical position sensor and a Windows personal computer operating system platform.	VOTA and the predicate employ substantially the same materials and technology.
Biocompatibility	The Predicate in its 510(k) Summary notes that it has no direct contact with	VOTA and its components including Microsoft Kinect has no	VOTA and the predicate do not come into contact with the patient. Neither

	patient and biocompatibility concerns are not applicable.	direct contact with patient. Biocompatibility concerns are not applicable.	presents biocompatibility safety concerns.
Compatibility with the environment and other devices / System Compatibility	The Predicate in its 510(k) Summary notes that its software and operating system requirements have been validated, and suitable change management and design controls have been implemented.	VOTA is a software system using Microsoft Kinect and the Windows personal computer platform. Together they have been validated to meet design requirements and conform to Standard of Care for the intended use. Appropriate GMP/QSR design controls and change management controls have been implemented.	Both VOTA and its predicate have been validated as compatible with a Windows personal computer and Microsoft Kinect sensor.

5.8 Safety Characteristics

The *BAI-VOTA-SYS-003 Risk Analysis* document (see Appendix E) describes the safety characteristics of VOTA, analyzed in accordance with ISO 14971 Medical Devices – Application of Risk Management to Medical Devices. This analysis informs the comparison to the predicate device that follows below.

Area of Comparison	Predicate	Applicant Device	Discussion
Electrical safety	The Predicate is a software device that does not touch the patient. Its electrical components are a personal computer and Microsoft Kinect sensor that the patient does not touch. These components comply with consumer electrical safety standards such as UL.	VOTA is a software device that does not touch the patient. Its electrical components are a personal computer and Microsoft Kinect sensor that the patient does not touch. These components comply with consumer electrical safety standards such as UL.	No differences in electrical technology and safety between VOTA and predicate.

Mechanical safety	As a software system, the Predicate does not utilize any mechanical components that the patient touches.	As a software system, VOTA does not utilize any mechanical components that the patient touches.	No differences in mechanical safety between VOTA and predicate. There are no mechanical safety concerns in either product.
Chemical safety	Not applicable to a software system.	Not applicable to a software system.	No differences between VOTA and predicate. Chemical safety is not an issue that applies to either product.
Thermal safety	No issues of thermal safety are identified in the Predicate's 510(k) Summary.	VOTA is a software system that uses a Windows personal computer and Microsoft Kinect. There are no known sources of heat except a small amount of warmth generated by the personal computer.	No differences between VOTA and predicate. Thermal safety is not an issue that applies to either product. No adverse impact to patient safety.
Radiation safety	The Predicate uses Microsoft Kinect that has an infra-red sensor that per the 510(k) Summary complies with laser Class 1 standard.	VOTA uses Microsoft Kinect that has an infra-red sensor that complies with the laser Class 1 standard and IEC safety standard 60825-1:2007.	No differences between VOTA and predicate. No adverse impact to the safety of patients using VOTA.
Sterility	The Predicate is a non-sterile product per the 510(k) Summary. It is a software system that uses Microsoft Kinect.	VOTA is a non-sterile product. It is a software system that uses Microsoft Kinect.	No differences between VOTA and predicate. Neither is intended to be a sterile product. No adverse impact to the intended use.

5.8.1 Level of Concern

The VOTA software system has a Moderate Level of Concern, which is the same as the Predicate. The rationale for the Moderate Level of Concern is that, prior to the mitigation of hazards, there is a small, but non-zero risk of Minor Injury (e.g. joint/muscle injury due to overexertion) for a patient if instructed to perform an inappropriate movement for the patient's specific therapy. This risk is

mitigated by the supervision of a medical professional that is stipulated in the device's Indications for Use. Since the supervision of a medical professional is considered a control, we must assert a Moderate Level of Concern.

5.9 Summary of Testing

The VOTA software system has been extensively tested, including bench and clinical testing.

5.9.1 Bench Testing

Third-party bench testing of the VOTA patient-facing application was conducted to establish that the software system provides the capabilities necessary to support the product's Indications for Use. In addition to validating the core functionality of the software system, this testing also establishes substantial equivalency to the Predicate, which shares (nearly) identical indications.

Traceability has been provided between: (1) the VOTA Indications for Use Statement; (2) a core set of system-level requirements; (3) test plans (including rubrics and success criteria) to validate that these system-level requirements; and (4) documented test results showing success criteria are met. A major emphasis of bench testing is demonstration of the consistency of VOTA exercises with Standard of Care for occupational therapy. Therefore, a detailed explanation of Standard of Care is provided, along with linkages to test plans and results. Analysis of bench test results demonstrates that all success criteria are met.

5.9.2 Risk Controls

Verification of risk controls has been provided within the Device Hazard Analysis and the *Risk Control Verification Plan*. The results of third-party evaluations verifying the recommended controls are documented in the *Risk Control Verification Report*. All risk controls have been successfully verified by use of tests and/or demonstrations and/or document review and inspection, with traceability maintained between potential hazards and V&V results.

5.9.3 Clinical Testing

Clinical testing was performed to demonstrate and validate the accuracy of the device and repetitive tasks. Clinical testing of the VOTA system was conducted by the University of Virginia (UVa) Department of Physical Medicine and Rehabilitation and the UVa HealthSouth Rehabilitation Hospital under the approval and governance of the UVa Institutional Review Board for Human Subject Research (IRB-HSR). In the IRB-approved protocol, stroke survivors with upper extremity (UE) impairment were asked to attend three one-hour sessions per week over eight weeks (24 total sessions for each subject) in the Outpatient Clinic of the UVa HealthSouth Rehabilitation Hospital. In these sessions, the patients employed the VOTA patient-facing application to practice virtual activities of daily living (ADLs) to exercise their upper extremity in repetitive task practice, consistent with Standard of Care for occupational therapy. Licensed occupational therapists supervised the sessions. Rubrics and success criteria included: (1) establishing clinically significant improvement in pre-/post- functional gain using gold-standard measures of UE motor performance; (2) assessment of usability using a widely-accepted instrument; (3) systematic comparison of VOTA to Standard of Care by licensed therapists, and (4) assessment of safety by experienced therapists with over 200 hours of actual patient contact time using the VOTA system.

Clinical testing demonstrated that use of VOTA is effective for supporting the rehabilitation of UE motor function, as measured by pre-/post- assessment using the Fugl-Meyer UE assessment (FMUE) - a widely-recognized, accepted, and clinically-relevant measure of post-stroke functional impairment. Results of clinical testing demonstrated that stroke patients (n = 15, > 3 months since stroke, and no longer in rehabilitation outside of the study) using the VOTA system for approximately one hour, three times per week, over an 8-week period achieved an average FMUE improvement of 6 points. Additionally, there were no adverse incidents or injuries over the entire period of actual VOTA use by the stroke patients in the clinical testing spanning 240 total sessions of approximately 1 hour each. The results demonstrate that VOTA, used as intended for repetitive task practice, supports the rehabilitation of upper extremity motor function in stroke patients.

Clinical testing, published in peer-reviewed literature by the VOTA team, has demonstrated that VOTA's Kinect-based upper extremity tracking produces valid results for the intended application. The VOTA Kinect-based tracking solution was found to be sufficient, both to permit patients to successfully perform virtual ADL exercises and to support derivation of speed-based motor performance metrics. References have also been provided for existing literature demonstrating the accuracy of Kinect-based upper extremity tracking.

These results demonstrate that VOTA is as safe and as effective as the predicate device.