JINTRONIX	JINTRONIX REHABILITATION SYSTEM (JRS) TRADITIONAL 510(k)

7. 510(k) Summary

7.1 Owner Information

Name:	Jintronix Inc.
Device common name:	Jintronix Rehabilitation System (JRS)
Address:	999 3rd Avenue, Suite 3400, Seattle, WA 98104
Phone:	1-514-754-6688
Fax:	*None*
Contact:	Mark Evin
Title:	Regulatory Affairs & Quality Assurance Head (RAQA)
Email:	mark@jintronix.com
Date of Preparation:	Jun 03, 2013

7.2 Regulatory Correspondent Information

Name:	AxSource Consulting Inc.
Address:	336 Bronte Street South, Suite 224-225 Milton, Ontario, L9T 7W6
Office Phone:	905-854-6059
Cell:	416-452-0100
Contact Person:	Ms. Navneet Sekhon, President
Contact Person:	Rachelle D'Souza, Regulatory Affairs Consultant
Email:	nav.sekhon@axsource.ca
Email	rachelle@axsource.ca

7.3 Device Information

Trade Name	Jintronix Rehabilitation System (JRS)
Common Name	software system utilizing optical position recording for rehabilitation exercises
Classification name	System, optical position/movement recording
Model Number	Version 1.0
510(k) Submitter / Holder	Jintronix Inc.
510(k) Number	K130847
Device Panel	Physical Medicine
Product Code	LXJ
Classification Regulation	None. Reason: JRS 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: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=4731

The device or software comprises of a client application called JRS Wave and a web application or portal called JRS Portal. The JRS is to be used with the Microsoft Kinect motion sensing technology.

JRS Wave includes medically recognized gaming exercises for rehabilitation, audio-visual feedback & graphic movement representations for patients. Using the Microsoft Kinect for Windows to track motion, JRS Wave records performance metrics providing them to qualified medical

professionals via JRS Portal. Medical professionals can monitor patient performance, assign or modify rehabilitation exercises in JRS Wave for their patients through the JRS Portal allowing for patients to perform their prescribed rehabilitation program even from the comfort of their home.

7.4 Predicate(s) / Substantially Equivalent Device(s)

General 510(k) information	Predicate Device(s) [510(k) summaries attached – Appendices 5 & 12]	
Trade Name	Peak Motus Motion Measurement System	Coda cx1 Motion Analysis System
Model Number	unknown	unknown
510(k) Submitter / Holder	Peak Performance Technologies Inc.	Charnwood Dynamics Limited
510(k) Number	K030714	K033514
Device Panel	Physical Medicine	Physical Medicine
Product Code	LXJ	LXJ

7.5 Intended 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 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 statements		Why differences do not affect safety & effectiveness of Jintronix device when used as labeled
JRS	Predicates	
Gaming exercises intended to elicit medically recognized rehabilitation exercises from patients	Do not provide gaming exercises intended to elicit medically recognized rehabilitation exercises from patients.	All JRS gaming exercises are medically recognized (by clinicians / medical professionals) to be physical rehabilitation exercises. This is supported by a clinical study and scientific references (refer to Performance – Clinical section). Safety & Effectiveness were considered in the device risk hazard analysis & in the

		Performance sections of the 510(k) package
Provides audio feedback	Do not provide audio feedback	Does not impact safety / effectiveness of JRS
Require patient assessment and exercise guidance from clinician / medical professional prior to any exercise prescription. Exercises prescribed include original JRS medically recognized exercises recommended and JRS exercises modified / customized by the medical professional.	Do not include such requirement	Extra precaution to ensure proper movement technique for home-use of JRS. This puts the JRS at an equivalent level of clinical supervision as clinician-directed home based rehabilitation exercises, which are widely recommended by scientific literature.

7.6 Comparative Summary of Technological Characteristics

The JRS and predicates are software / hardware systems that share in common an intended use / indications for use, target populations, anatomical sites, location of use and technological characteristics like principle of operation, design and technology used. All the devices are intended for the physical rehabilitation of patients with orthopedic and neurological conditions. All the devices track limb and body motion, however, JRS body motion tracking is limited to the upper extremity and trunk. All the devices provide visual feedback, process and report on kinematic parameters measured like velocity and joint angular change during movement. JRS provides additional safety and convenience of use in being a prescription use device that enables home based rehabilitation exercises with remote medical professional control. JRS and predicates make use of optical motion sensing technology and a computer operating system. JRS and the predicates also neither deliver energy to patients nor pose any issues in terms of electrical, chemical, mechanical, thermal, radiation safety or compatibility. JRS is validated for system compatibility and performance. There were no issues for JRS in relation to human factors as safety, accuracy performance / effectiveness and usability were thoroughly considered.

The following is a comparison of the technological characteristics between the JRS and those of the predicate devices.

	Predicate Device(s) [510(k) summaries attached]		Jintronix Rehabilitation System (JRS)	JRS and Predicate(s) Discussion
	Peak Motus Motion Measurement System[1]	Coda cx1 Motion Analysis System[2]		
Technological Characteristics Comparison				

	Predicate Device(s) [510(k) summaries attached]		Jintronix Rehabilitation System (JRS)	JRS and Predicate(s) Discussion
	Peak Motus Motion Measurement System[1]	Coda cx1 Motion Analysis System[2]		
Principles of Operation	This system tracks and provides visual feedback of patient movement while reporting on kinematic parameters such as velocity and joint angles measured during movement.[1]	Information from the Coda website reveals human performance under professional supervision. As there are no visual movement cues provided by the Coda, it is possible to assume, from the location of use and lab set up video that the guiding clinician tells the patient what movement activities to perform.[7, 8] Movements performed are tracked, recorded, and analyzed by the Coda[2].	The JRS system allows a medical professional to assign movement activities to patients. Like the Peak Motus[1] and the Coda[2, 7], the JRS tracks upper extremity and trunk movement providing visual feedback of patient movement and reports on kinematic parameters like velocity and joint angular changes during movement.	No difference between JRS and predicates.
Energy Used / Delivered	Electrical energy used by hardware is variable due to various video input technologies. No energy is	Electrical energy is used by both CODA units and by the active infra-red emitting markers.[6] No energy is delivered into the subject as there is no	Not applicable as JRS is a software product. The Kinect for use with the JRS for optical motion capture is owned and	Not applicable to JRS, a software product. Energy used by external hardware (Microsoft

	Predicate Device(s) [510(k) summaries attached]		Jintronix Rehabilitation System (JRS)	JRS and Predicate(s) Discussion
	Peak Motus Motion Measurement System[1]	Coda cx1 Motion Analysis System[2]		
	delivered into the subject.[1]	electrical connection to the patient.[2]	distributed by Microsoft Inc. and uses only 12 watts of energy. No energy is delivered into the subject.	Kinect) has no negative impact to safety.
Human Factors	No comment on human factors in 510(k) summary.[1] Erroneous marker / sensor placement on patients can pose safety hazard in parametric data analysis. Multi-component system may pose usability issues.	No comment on human factors in 510(k) summary.[2] Erroneous marker / sensor placement on patients can pose safety hazard in parametric data analysis.[6] Multi-component system may pose usability issues.	No safety concern as no direct contact of JRS / Kinect with patients. External hardware, Microsoft Kinect is a Class I laser posing no safety issue. JRS prescription and remote medical professional monitoring of patients allows safe home based rehabilitation exercises. JRS has been validated for accuracy / performance effectiveness both clinically (*section 22*) and through software testing with appropriate change	Safety, accuracy, effectiveness and usability have been considered thoroughly by Jintronix.

	Predicate Device(s) [510(k) summaries attached]		Jintronix Rehabilitation System (JRS)	JRS and Predicate(s) Discussion
	Peak Motus Motion Measurement System[1]	Coda cx1 Motion Analysis System[2]		
			management and design controls (*section 18*). The JRS also incorporates correction of error in Kinect motion sensing to achieve optimal Kinect accuracy (*section 18.4*). Usability & Effectiveness consideration: JRS was predominantly recommended by medical professionals for the physical rehabilitation of their patients (*section 22.1, table 3*).	
Design	The system uses off-the-shelf video cameras, sensors, and computers to collect, quantify, and document human movement in two-dimensional or three-dimensional space. It includes additional	The technology includes components for capturing three-dimensional movements of patients, acquiring the data into a host PC, analyzing and processing the data, and displaying the	Refer to *section 18.3*. Like the predicates, JRS design also requires optical motion sensing technology and computer operating system with Windows for operation.	Similar design consideratio ns employed by JRS and predicates.

	Predicate Device(s) [510(k) summaries attached]		Jintronix Rehabilitation System (JRS)	JRS and Predicate(s) Discussion
	Peak Motus Motion Measurement System[1]	Coda cx1 Motion Analysis System[2]		
	components for processing the kinematic data, and displaying it graphically.[1]	data graphically.[2]		
Materials / Technology used	The system comprises of various software and hardware components which are used with a Microsoft Windows computer workstation. Refer to 510(k) summary for details.[1]	Codamotion software with following hardware: • the 'CODA' unit[3]: the optical capture component • the active infrared-emitting markers[3] mounted on the user's body • marker drivebox[3]: required in order to power the markers • charger tray[3] • codamotion hub[3]: in order to provide power to the CODA unit • RS422 data cable[3]	Jintronix Rehabilitation System (JRS) comprises of JRS Wave (client application software) & JRS Portal (web portal). The JRS is to be used with the Kinect for optical motion capture and a Microsoft Windows computer workstation.	Materials as indicated. Optical motion sensing technology and computer system common to JRS and predicates.
Biocompatibility	Not Applicable to JRS and predicates. JRS / Kinect has no direct contact with patient.			

	Predicate Device(s) [510(k) summaries attached]		Jintronix Rehabilitation System (JRS)	JRS and Predicate(s) Discussion
	Peak Motus Motion Measurement System[1]	Coda cx1 Motion Analysis System[2]		
Compatibility with the environment and other devices / System Compatibility	The system is compatible with Microsoft Windows.[1]	The system is compatible with any standard desktop or laptop machine running Microsoft Windows 98, NT, ME, 2000, XP. A processor speed of at least 500MHz is recommended. The host PC must have one serial port interface for each CODA unit; these can be RS-232 or RS-422.[4]	The compatibility of JRS software with Kinect hardware and computer operating system requirements have been validated. Suitable change management and design controls have been implemented (see *section 17*).	JRS is validated software.
Safety				
Electrical safety	No energy is delivered into the subject.[1]	No energy is delivered into the subject as the system is non-invasive with no electrical connection to the user.[2] Refer to standards below.	Not applicable as JRS is a software product. Like both predicates, no energy is delivered into the subject. Like both predicates[1, 2], the JRS is non-invasive. The Kinect for use with JRS is	Not applicable to JRS, a software product. Energy used by external hardware (Microsoft Kinect) has no negative impact to safety.

	Predicate Device(s) [510(k) summaries attached]		Jintronix Rehabilitation System (JRS)	JRS and Predicate(s) Discussion
	Peak Motus Motion Measurement System[1]	Coda cx1 Motion Analysis System[2]		
			owned and distributed by Microsoft Inc. and uses only 12 watts of energy.	
Mechanical safety	Per the 510(k) summary, safety is not an issue.[1]	Markers and their associated drive boxes are attached to the subject being studied using medical double sided adhesive tape.[5] Codamotion documentation[2, 4, 5] does not cite issues regarding mechanical safety.	Not applicable as JRS is software.	No issue of mechanical safety to JRS system.
Thermal safety	Undisclosed in 510(k) summary[1] but system components do not provide for thermal safety concern.	Per the 510(k) summary[2], this system does not produce sources of localized heat so no thermal safety hazard arises.	Not applicable as JRS is software.	No issue of thermal safety for the JRS system.
Chemical safety	Not applicable. Software and hardware system.[1]	Not applicable. Software and hardware system.[2]	Not applicable. Software only.	No differences

	Predicate Device(s) [510(k) summaries attached]		Jintronix Rehabilitation System (JRS)	JRS and Predicate(s) Discussion
	Peak Motus Motion Measurement System[1]	Coda cx1 Motion Analysis System[2]		
Radiation safety	Passive sensors are used. Per the 510(k) summary, safety is not an issue.[1]	LED markers are used[4, 5]. No ionizing radiation generated.[2]	Microsoft™ Kinect used with the JRS emits infra-red radiation but complies with Class 1 laser standard.	No adverse impact to safety of patients using JRS
Sterility	JRS and predicates[1, 2] are non-sterile products. JRS is a software system that uses Microsoft Kinect and a computer operating system. Both predicates are software and hardware systems.			

References in SE Discussion

[1] FDA 510(k) Database. *Peak Motus Motion Measurement System. 510(k) Summary* (attached). Retrieved May 1, 2013, from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=11114

[2] FDA 510(k) Database. *Coda cx1 Motion Analysis System. 510(k)* Summary (attached). Retrieved May 1, 2013, from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=13571

[3] Codamotion website. *Hardware Components*. Retrieved May 16, 2013, from http://www.codamotion.com/product-catalogue/hardware-components.html

[4] Codamotion System User Guide.. Retrieved May 19, 2013,, from http://www.codamotion.com/forum/docs/uploads/Codamotion%20System%20UserGuide-7%20Sept%202011.pdf. 9.

[5] Codamotion System User Guide. Retrieved May 19, 2013, fromhttp://www.codamotion.com/forum/docs/uploads/Codamotion%20System%20UserGuide-7%20Sept%202011.pdf. 11.

[6] Codamotion website. *Technology Overview*. Retrieved May 16, 2013, from http://www.codamotion.com/systems/technology-overview.html

[7] Codamotion website. *Clinical Movement Analysis*. Retrieved May 16, 2013, from http://www.codamotion.com/applications/clinical.html

[8] Codamotion website. *Advantages and Capabilities*. Retrieved May 16, 2013, from http://www.codamotion.com/applications/clinical/advantages-and-capabilities.html

† Notation on the Motus 10 web references (3, 4, 5):

The design of the Peak Motus Motion Measurement System approved by CDRH on May 16, 2003[1] allowed the use of off-the-shelf cameras technologies and was compatible to run on Microsoft Windows. It is in these areas that the system was changed when acquired by Vicon Inc. Beside a name change to Vicon Motus 10, the system was made adaptable to the latest computer operating systems, Windows 7 and 8 and incorporated camera technologies of Contemplas Templo[5].

The Motus 10 web references # 4 and # 5 concur with the information in the 510(k) summary approved by CDRH[1]. Only reference # 3 is solely relied on to indicate target patients with orthopedic and neurologic conditions. As the approved 510(k) summary[1] lists physical rehabilitation in the indications for use, it is reasonable to assume that the original Peak Motus Motion Measurement System was used for patients with neurologic and orthopedic conditions. Therefore, the changes to the CDRH approved Peak Motus Motion Measurement System does not impact the SE demonstration.

7.7 Predicate Device(s) Non Clinical Summary for Substantial Equivalence Determination

This section is not applicable as no non clinical study for either predicate was used for substantial equivalence determination.

7.8 Clinical Performance Data

Clinical Trial Design

A clinical study was conducted in Canada to study the movements recorded by the JRS and verify that they were rehabilitation movements. The clinical study involved a video recording of 20 healthy adult subjects, men and women of various ages that were required to perform the customized JRS rehabilitation program developed in consultation with clinicians. The video recording meant for clinician assessment focused on the subject and excluded the software and hardware involved, thereby eliminating potential clinician distraction and bias that may have occurred if the clinician liked the software seen in the video. The video was edited to remove unnecessary time gaps between JRS exercises and split into 4 videos for assessment by 4 clinicians (physical and occupational therapists). All raw and edited video footage were backed up and stored on a secure remote server. The 4 videos were uploaded to the web for clinicians to access through a private

URL. Each clinician accessed one video and completed 50 online questionnaires (10 activity components per subject x 5 subjects). Each questionnaire asked clinicians

1. To select the movement(s) seen in the video from a list of all JRS supported rehabilitation movements
2. Identify any potential risks for their patients posed by the movements seen in the video and
3. Whether they would recommend the movement seen in the video to their patients.

Safety & Effectiveness Summary

The clinical study results were predominantly 100% exceeding the 80% acceptance criterion for all JRS activity movements demonstrating that the JRS movements are clinician recognized rehabilitation movements and validating the accuracy of the JRS in data processing. The use of JRS movements in the rehabilitation of the intended patient populations have been supported by scientific literature and clinical guidelines. Please refer to *section 22.3 Performance Testing – Clinical.*

As part of study, clinicians identified the following potential risks, their corresponding vulnerable patient populations and mitigation options (Table 2). As a result, Jintronix has updated labeling accordingly (*section 15 Proposed Labeling*).

Table 2: JRS Movements - Potentials Risks, Vulnerable Patient Populations and Mitigation Options

Potential Risk(s)	**Vulnerable Patient Population(s)**	**% Clinicians' responses [n=200 (20 subjects x 10 JRS activity components)]**	**Mitigation option(s) for clinicians**
Falls	Balance Deficits	24.5%	Modify JRS rehabilitation program to reduce movement range Clinician intervention prior to JRS use Clinician advises non use of sitting balance, standing and pop clap activities of JRS.
Shoulder Pain / Impingement	Geriatric	21%	Clinician intervention prior to JRS use
Back Pain	Patients with back injuries	2.5%	
Knee Injury	Geriatric Patients with knee injury / surgery	5%	Modify JRS rehabilitation program to reduce movement range, number of movement repetitions Clinician intervention prior to JRS use Clinician advises non use of standing activity of JRS

Feedback from clinicians as to whether they would recommend the JRS movements (demonstrated during the clinical trial) to their patients was reported (Table 3).

Table 3: Clinicians Recommendations of JRS Movements

% Clinicians responses [n=200, (20 subjects x 10 JRS activity components)]	Clinicians recommendations of JRS movements in videos
88%	Fully recommended
8.5%	Recommendation depends on patient ability
3.5%	Not recommended without clinician intervention

Adverse Effects

No adverse effects were reported as expected by study subjects.

7.9 Non Clinical & Clinical Conclusions

The Canadian clinical study demonstrates that the JRS movements are medically recognized rehabilitation movements. The study results also validate the accuracy of the JRS in data processing. Scientific literature in *section 22.3 Performance Testing – Clinical* further supports the use of JRS movements in the rehabilitation of the patient populations in the JRS intended use.

7.10 Other Information

Kinect Precision

Jintronix with McGill university researchers won a grant from the National Sciences and Engineering Research Council of Canada to conduct a study to determine the accuracy of the Kinect. Kinect's accuracy was determined in terms of kinematics over a range of distances between the Kinect and the user. In the study, the Kinect was compared to the Optotrak, a gold standard in motion sensing technology with a reported precision of less than 0.5mm.

Jintronix Compliance to FDA Quality System Regulation (QSR) 21 CFR 820

Jintronix has implemented a quality system in accordance with FDA's Quality System Regulation 21 CFR 820. Standard Operating Procedures relevant to this 510(k) have been referenced herein.

7.11 This summary

- includes only information that is also covered in the body of the 510(k).
- does not contain any puffery or unsubstantiated labeling claims.
- does not contain any raw data, i.e., contains only summary data.
- does not contain any trade secret or confidential commercial information.
- does not contain any patient identification information.

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

February 28, 2014

Jintronix, Inc.
c/o Navneet Sekhon
AxSource Consulting, Inc.
336 Bronte Street South, Suite 224-225
Milton, Ontario L9T 7W6
CANADA

Re: K130847
Trade/Device Name: Jintronix Rehabilitation System
Regulatory Class: Unclassified
Product Code: LXJ
Dated: January 22, 2014
Received: January 23, 2014

Dear Mr. Sekhon:

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 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,

Carlos L. Pena -S

Carlos L. Peña, Ph.D., M.S.
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 on last page.

510(k) Number *(if known)*
K130847

Device Name
Jintronix Rehabilitation 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 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.

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)

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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos L. Pena -S

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