K103245

APR - 5 2011

## 510(k) Summary
**As required by section 807.92(c)**

**Device Description**:

| | |
|---|---|
| Device Trade Name: | Integrity Spinal Care System |
| Model Number | ICSC 2.0 |
| Common Name: | Traction Equipment |
| Classification Name: | Power Traction Equipment |
| Classification Panel: | Physical Medicine |
| Class and Reference | Class II (21 CFR Section 890.5900) |
| Product Code: | 89 ITH |

**Applicant/Official Contact Person:**
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**Submitter /Manufacturer:**
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Prepared on 8/20/2010

**Predicate Devices**:

Integrity Life Sciences is making the claim that Integrity Spinal Care System is substantially equivalent to the predicate devices listed below:

| **Legally Marketed Predicate Device** | **Manufacture Name** | **Regulatory Class and Product Code** | **510(K) Registration Number** |
|---|---|---|---|
| Vax-D Genesis G2 System | Vax-D-Medical Technologies LLC | Class II/ITH | K071347 |
| DRX5000 | Axiom USA Inc. | Class II/ITH | K023160 |

The rationale of declaring the Integrity Spinal Care System substantially equivalent to the above two predicate devices are based on the following:

**Technological Characteristics**

The Integrity Spinal Care System incorporates the same/ similar principles and working characteristics of the predicate devices, the DRX5000 (K023160) and the VAX-D G2 Genesis System (K071347) and is similar in size, shape and function. There are similar key design technical characteristics; multi-function distraction table designed to applied distraction forces and controlled by a computer console, same/similar components for treatment and measurement; similar size, power source, and performance. The Integrity Spinal Care System has similar components to the DRX5000 (K023160) and has proven to be safe through testing.

**Summary of Safety and Effectiveness**

The operating principles of the Integrity Spinal Care System are similar/same DRX5000 (K023160) and the VAX-D G2 Genesis System (K071347) which permit the application of accurately controlled distraction tension to the lumbar and cervical spine in order to decompress the intervertebral discs and spinal structures. Disc decompression is defined as unloading due to distraction and positioning. The important basic parameters contributing to the safety and effectiveness of the device include the smooth and gentle logarithmically applied distraction tensions, the smooth logarithmic release rate of tensions and relaxation cycles, the cyclic periodicity, the upper limits on distraction tensions, and in additions, the positioning of the patient and the means of fixing the upper body. The important safety factors are patients can immediately by pressing the patient hand held safety switch.

**Proposed Intended Use**

The Integrity Spinal Care System provides a program of treatments for relief from pain for those patients suffering with low back pain or neck pain. Each treatment consists of a physician prescribed treatment period on the Integrity Spinal Care System and is designed to provide static, intermittent, and cycling distraction forces to relieve pressures on structures that may be causing low back or neck pain. Conditions that may be treated include neck pain and back pain associated with herniated discs, protruding discs, degenerative disc disease, posterior facet syndrome, and sciatica. It achieves these effects through decompression of intervertebral discs, that is, unloading due to distraction and positioning.

**Indications for use**

The Integrity Spinal Care System provides a primary treatment modality for the management of pain and disability for patients suffering with spinal pain conditions. It has been found to provide relief in a variety of conditions involving anatomical dysfunctions of the spine that generate localized pain as well as peripheral radiation, including patients with protruding or herniated intervertebral discs as well as those with acute facet problems and sciatica.

**Summary of Key Descriptive Elements**:

The key elements of the Integrity Spinal Care System are as follows:

1. The bed is a stand on/stand off tilt type bed that allows the fully clothed patient to step onto a footrest while it is in near vertical position. The bed and patient can then be slowly lowered to the horizontal treatment position using a remote controller hand held by the practitioner.

2. The bed is split into two cushions, each slide able in the horizontal plane only on low friction runners and each being able to be locked independently.
3. The patient lies in a supine position on the table with the legs support with removable knee pillows.
4. Distraction tensions are applied to the patient via a head or pelvic harness.
5. The lower cushion, which is unlocked and on which the patient's lower trunk is rested, is able to slide easily thus reducing almost completely any frictional movement between patient and bed cushion when distraction tensions are applied, this concentrates virtually all the forces to the affected part of the lumbar spine.
6. The traction unit is mounted to both ends of the bed the belt pulley system is attached to a vertical movable platform incorporated into the tower. This enables the distraction tensions to be applied at differing angles to the patient.
7. The traction unit is programmed and controlled from a control panel fitted into the tower to give static or intermittent distraction.
8. The minimum and maximum distraction settings are 10-200 lbs. (lumbar 10-150 lbs, cervical 5-50 lbs)
9. Treatment parameters i.e. tensions and time are continuously monitored and shown by LCD readout at the time of treatment set up and during treatment.
10. At the conclusion of treatment time, tension always returns to zero.
11. A DVD player, which is incorporated in a separate section of the control panel, and headphones provide comfort and relaxation to the patient and provides and opportunity for patient education via clinical tapes.
12. There is instantaneous release of all tensions if the patient pushes the button on the hand held Patient Safety Switch, or the Stop Button, or Emergency Stop on the control panel has been pushed by the practitioner.
13. The Integrity Spinal Care System will not operate if the Patient Safety Switch is not working properly or has not been tested prior to each treatment.
14. The treatment cannot be restarted when a patient activates the Patient Safety Switch or the Stop Button has been pushed during treatment unless all treatment parameters are manually re-entered into the controller.

**Summary of Safety Features**

The more important safety features of the Integrity Spinal Care System include:

1. The activation of actuators for the bed is via a 24-volt electrical circuit.
2. The control circuitry for the distraction unit including the power supply to the Patient Safety Switch is a maximum 24 volts.
3. The patient steps onto the bed while it is in the vertical position and is then reclined into the treatment position under the supervision of the attendant, and does not have to climb onto the treatment bed.
4. Adjustable handgrips hand grips are fitted for patient support during the reclining o the bed.
5. There is instantaneous release of all tensions when the button on the hand held Patient Safety Switch is depressed, the Stop Button is pressed on the control panel, or when electrical current is interrupted. The treatment program has to be manually reentered into the control panel before treatment can re-commence.
6. All treatment parameters must be manually entered each time a treatment occurs.
7. There is a permanent, visible means of indication of the angle of distraction pull.
8. The system does not allow manual override the maximum intended tension of 150 1bs for lumbar session and 50 1bs for a cervical session.

**Non-clinical Tests:**

The Integrity Spinal Care System is as safe and effective as the predicate devices demonstrating compliance to FDA recognized Consensus Standards. A calibrated dynamometer was placed between the tower and bed to stimulate a patient. Measurements of tension demonstrate that the tension readings displayed and noted from the calibrated dynamometer are comparable to predicate devices.

The device is in compliance with the following safety standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995
- IEC 60601-2-38 1996/Amendment 1:1999, Medical electrical equipment - Part 2-38: Particular requirements for the safety of electrically operated hospital beds.
- IEC 60601-1-2:2001 Medical Electrical Equipment Part 1 - 2: General requirements for Safety - Collateral Standard, Electromagnetic Compatibility – Requirements and Tests
- The Integrity Spinal Care System has been reviewed for risk management utilizing ISO 14971:2007, Application of risk management to medical devices ensuring all aspects of the device are reviewed for potential hazards

**Conclusion:**

The comparisons to the predicate devices demonstrate that the proposed device is safe and effective and does not raise any new potential safety risks and is substantially equivalent to the predicate devices. The subject device and the predicate devices are substantially equivalent in the areas technical characteristics, general function, application, intended use, indications for use, and performance testing data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
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Newtown, Connecticut 06470

APR - 5 2011

Re: K103248
Trade/Device Name: Integrity Spinal Care System
Regulation Number: 21 CFR 890.5900
Regulation Name: Power traction equipment
Regulatory Class: Class II
Product Code: ITH
Dated: March 29, 2011
Received: March 31, 2011

Dear Mr. Borsai:

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 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,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known):

Device Name: Integrity Spinal Care System

**INDICATIONS FOR USE**

The Integrity Spinal Care System provides a program of treatments for relief from pain for those patients suffering with low back pain or neck pain. Each treatment consists of a physician prescribed treatment period on the Integrity Spinal Care System and is designed to provide static, intermittent, and cycling distraction forces to relieve pressures on structures that may be causing low back or neck pain. Conditions that may be treated include neck pain and back pain associated with herniated discs, protruding discs, degenerative disc disease, posterior facet syndrome, and sciatica. It achieves these effects through decompression of intervertebral discs, that is, unloading due to distraction and positioning

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices



510(k) Number K103248