INTEGRITY LIFE SCIENCES

FEB - 6 2014

K130249

510(k) Summary

As required by section 807.92(c)

Device Description:

Device Trade Name:	Integrity Spinal Care System 3.0
Model Number	ICSC 3.0
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: James J. Gibson, Jr.
Integrity Life Sciences
Tel. (813) 935-5500 / Fax (935) 5505

Submitter /Manufacturer:
(This is the only manufacturing site.)
Integrity Life Sciences
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Tampa, Florida 33612
Tel. (813) 935-5500 / Fax (935) 5505

Prepared on December 30th 2013

Conforming Standards:

EMC: IEC 60601-1 2nd Edition: 1988
IEC 60601-1-2 2nd Edition: 2001
ISO 14971 : 2007

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
DRX9000 True Non Surgical Decompression System	Axiom Worldwide, LLC.	Class II/ITH	K060735

Technological Characteristics

The Integrity Spinal Care System 3.0 incorporates the same principles and working characteristics of the predicate devices, the DRX9000 True Non Surgical Decompression System (K060735) and is same in size, shape and function. The components of The Integrity Spinal Care System 3.0 are substantially equivalent in form, fit, function and configuration to its predicate device the DRX9000 True Non Surgical Decompression System (K060735).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 3.0 is essentially the same product as the predicate device the DRX9000 True Non Surgical Decompression System (K060735), however, Integrity Life Sciences has made some modifications to the appearance. Those changes were evaluated by an independent party, through testing, and found not to impact the safety and effectiveness of this device. The Integrity Spinal Care System 3.0 has the same components to the DRX9000 True Non Surgical Decompression System (K060735) and has proven to be safe through testing.

The Integrity Spinal Care System 3.0 delivers accurately controlled tensions in the same manner as its predicate device the DRX9000 True Non Surgical Decompression System (K060735) designed to relax paraspinal muscles and allow distractive forces to decompress intervertebral spinal disc space. Integral to effective spinal decompression and included in the Integrity Spinal Care System 3.0 and its predicate device the DRX9000 True Non Surgical Decompression System (K060735) are continuous load-cell tensile feedback into the treatment computer, dedicated and matched servoamplifier and servo-motor, smoothly modulated cyclic tension application (high and low tension plateaus transitioned into via non-linear tension change), two segment (upper and lower) textile patient harness, patient safety switch, and free-floating lower body mattress. An important safety feature designed into The Integrity Spinal Care System 3.0 and its predicate the DRX9000 True Non Surgical Decompression System (K060735) is patients hold a patient safety switch to allow at anytime the pausing of any tensile forces.

Summary of Safety and Effectiveness

The operating principles of the Integrity Spinal Care System 3.0 is similar/same the DRX9000 True Non Surgical Decompression System (K060735) which permit the application of accurately controlled distraction tension to the lumbar 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 factor is patients can stop the treatment by pressing the patient hand held safety switch.

Proposed Intended Use

The INTEGRITY CARE SYSTEM 3.0 provides a program of treatments for relief from pain for those patients suffering with low back pain. Each treatment consists of a physician prescribed treatment period on the INTEGRITY CARE SYSTEM 3.0 and is designed to provide static,

intermittent, and cycling distraction forces to relieve pressures on structures that may be causing low back pain. It relieves 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 CARE SYSTEM 3.0 provides a primary treatment modality for the management of pain and disability for patients suffering with incapacitating low back pain and sciatica. It is designed to apply spinal decompressive forces to compressive and degenerative injuries of the spine. It has been found to provide relief of pain and symptoms associated with herniated discs, bulging or protruding intervertebral discs, degenerative disc disease, posterior facet syndrome, and sciatica.

Non-clinical Tests:

The Integrity Spinal Care System 3.0 is as safe and effective as the predicate device 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 60601-1-2:2001 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 non clinical comparisons of the Integrity Spinal Care System 3.0 to its predicate device the DRX9000 True Non Surgical Decompression System (K060735) demonstrates that the proposed device is substantially equivalent in the areas technical characteristics, general function, application, intended use, indications for use, and performance testing data. No clinical data was required for this 510(k) clearance.

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 6, 2014

Integrity Life Sciences
James J. Gibson, Jr., Ph.D
2189 W Busch Blvd.
Tampa, FL 33612

Re: K130249
Trade/Device Name: Integrity Spinal Care System 3.0
Regulation Number: 21 CFR 890.5900
Regulation Name: Power traction equipment
Regulatory Class: Class II
Product Code: ITH
Dated: December 30, 2013
Received: January 2, 2014

Dear Dr. Gibson:

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. Peña -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

Indications for Use

510(k) Number (if known): K130249

Device Name: Integrity Spinal Care System 3.0

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

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Carlos L. Peña S