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Press Release

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FOR IMMEDIATE RELEASE

Integrity Life Sciences Receives US FDA 510(k) Clearance for its Integrity Spinal Care System Medical Device

TAMPA, FL, USA, JULY 9, 2012: Integrity Life Sciences announced today that on April 5th, 2011, the US Food and Drug Administration issued to Integrity Life Sciences a 510(k) that permits Integrity to legally market their recently developed medical device in the USA. Integrity is also the manufacturer and together with efforts of Third Party Reviewer, TUV Rheinland of North America, the Integrity Spinal Care System is the newest device in America to achieve this regulatory decision as it pertains to similarly marketed devices. The FDA 510(k) was issued from the US FDA's, Division of Surgical, Orthopedic and Restorative Devices, Office of Device Evaluation, Center for Devices and Radiological Health.

The theory behind non-surgical spinal decompression is a process whereby forces are applied to the spine in a manner that maximizes spinal elongation. Spinal elongation is maximized when paraspinal muscles, the muscles that guard the spine from injury, are relaxed. When paraspinal muscles relax, applied spinal decompressive forces spread apart the bony vertebra of the spine. This relieves pressure on nerves and intervertebral discs. Where this spinal elongation occurs, pressure drops within the disc which facilitates movement of fluid, carrying nutrients and oxygen inside the disc. Additionally, the reduction in pressure can help draw in herniated disc fluids, reducing the size of the herniation. Integrity Life Sciences delivers an advanced solution to address one of the most costly systemic ailments in the world, chronic low back and neck pain. The *ISCS 2.0* and *Lombare Systems* are non-surgical spinal decompression therapy systems engineered to provide pain relief for compressive and degenerative conditions of the spine.

The US FDA 510(k) # k103248 Intended Use reads as follows: *"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."*

One of the previously marketed machines noted as a qualified and substantially equivalent predicate device was the DRX 5000 (marketed as a DRX9000 combo or the DRX9000C) by Axiom Worldwide, Inc. Mr. James Gibson is the President & CEO of Integrity Life Sciences and he is also the original founder and President of Axiom Worldwide, Inc, the originator of all DRX 9000 devices. While serving at Axiom, Mr. Gibson was the submitter of all of Axiom Worldwide's US FDA 510(k)s and he is also the submitter of Integrity's.

Prior to formal submission to the US FDA, Integrity submitted its application to TUV Rheinland of North America. According to its literature, TUV Rheinland was established in 1872 and just recently celebrated its 140th year in business. As one of the oldest testing and certification companies in the world, TUV Rheinland maintains 500 locations in more than 60 countries. According to Mr. Gibson of Integrity, *"Quite simply, TUV was chosen to undertake the challenge of validating our application and testing data because they are the best in the business with the reputation, credentials and integrity that a medical device manufacturer needs in today's competitive marketplace."*

Integrity Life Sciences is a privately held USA based company with international partners located across the globe with a mission of *"Restoring Integrity to the Spine"*. For additional information please visit: www.IntegrityLifeSciences.com. To schedule an interview please contact: James Gibson, President & CEO at: telephone: 001-813-935-5500 or email: James@IntegrityLifeSciences.com.



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