

Representatives from Axiom Worldwide and Integrity Life Sciences to Assist FDA on Guidance Committee

TAMPA, FLORIDA, USA, March 4, 2016 /EINPresswire.com/ -- The Food and Drug Administration (FDA), Center for Devices and Radiological Health, today announced the establishment of a



committee on the medical device industry and healthcare community that refurbish, recondition, rebuild, remarket, remanufacture, service, and repair medical devices and representatives from Axiom Worldwide and Integrity Life Sciences will be offering assistance to the committee and its endeavors in the coming weeks and months.

Axiom Worldwide and Integrity Life Sciences has been embroiled in federal litigation over the repeated violations of their Intellectual Property Agreements. "As a company who has had their products essentially stolen in direct violation of Federal Courts and illegally proliferated across many segments of the market, we can appreciate the FDA's approach to this troublesome task as it seeks ways to stop the adulteration of illegal products that may impede patient safety standards that legitimate manufacturers abide by," commented President and CEO, Jim Gibson.

The FDA is taking this action, in part, because various stakeholders have expressed concerns about the quality, safety, and continued effectiveness of medical devices that have been subject to one or more of these activities that are performed by both original equipment manufacturers (OEM) and third parties, including health care establishments. The FDA is seeking guidance after recently expressing concerns that some third-party entities who refurbish, recondition, rebuild, remarket, remanufacture, service, or repair medical devices may use unqualified personnel to perform service, maintenance, refurbishment, and device alterations on their equipment, and that the work performed may not be adequately documented. Possible public health issues arising from these activities include ineffective recalls, disabled device safety features, and improper or unexpected device operation.

Integrity Life Sciences delivers a multitude of orthotic treatment options to address one of the most costly systemic ailments in the world, chronic low back and neck pain. Our advanced solution begins with the Integrity Spinal Care System (ISCS) ™ and its proprietary iELCiPS Technology™. The ISCS non-surgical spinal decompression modality systems are engineered to provide pain relief for compressive and degenerative conditions of the spine. Specifically, 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.

As a compliment to the ISCS, Integrity offers the very effective Integrity Gel Support Brace™. Our advanced lumbar support brace is a fitting compliment to non-surgical spinal decompression therapy and was designed as an adjunct therapy for those suffering from back pain due to disc related conditions. The Integrity Gel Support Brace may be used with or without Integrity's non-surgical spinal

decompression systems and is an excellent treatment option for the patient to use at home.

In addition, Integrity Life Sciences has been exclusively granted the use of all of the technology, products, US Patent and Trademark Office's assignments, logos and other forms of intellectual property that were created by Axiom Worldwide, INC under the leadership of Jim Gibson from Tampa, Florida. The agreement specifically includes the flagship product DRX9000[™], its family of products, and all of its derivatives such as the DRX9000C. Integrity offers support for these products, which includes: sales, maintenance services, and repairs. Only Integrity Life Sciences is Registered with the US FDA as a Factory Authorized - Contract Manufacturer - for Axiom Worldwide and the DRX9000 True Non-Surgical Spinal Decompression Systems[™]

James Gibson, President of Integrity Life Sciences states "Our partners, in over 50 countries and territories, have the unique opportunity to present a cutting edge medical device, utilizing a clinically validated protocol that restores a patient's quality of life non-surgically and without pharmaceutical or invasive intervention". With a body of published clinical research from around the world will support and strengthen your sales presentation; members of our medical advisory board herald from prestigious institutions such as Johns-Hopkins and The Mayo Clinic just to name a few. In addition, partners will have confidence in a quality product that adheres to the stringent standards mandated by FDA, CE, and ISO. Sales, marketing, and technical training is offered in prestigious locations in Europe, Asia, the Middle East and throughout the United States.

Learn more @: www.IntegrityLifeSciences.com or www.AxiomWorldwide.com

Integrity Life Sciences, LLC and Axiom Worldwide, INC are privately held companies with global partners and shareholders 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 Integrity Life Sciences 813-935-5500 email us here

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