

# PRESS RELEASE



## **Aperion Biologics, Inc. Granted CE Mark for Z-Lig ACL Replacement Device**

*Off-the shelf biologic medical device is now approved and poised for introduction in the EU for use in certain anterior cruciate ligament (ACL) knee surgeries*

San Antonio, TX – April 22, 2014 - Aperion Biologics, Inc. was granted the CE Mark approval for its lead product, the Z-Lig™ ACLR device, to be used by surgeons in the European Union and other territories that accept the CE Mark.

The Z-Lig™ is the first engineered biologic device for treatment of revision and multiligament anterior cruciate ligament (ACL) knee reconstruction to be granted a CE Mark or to be approved anywhere worldwide.

Aperion conducted a prospective, randomized, controlled clinical trial in Europe and South Africa that demonstrated biological acceptance of its bioengineered porcine tendons, re-establishment of knee stability, and remodeling over time into the patient's own human ligament. U.S. clinical evaluation is pending final discussions with the FDA on its approved pivotal clinical study of the Z-Lig™.

Over 600,000 ACL reconstruction surgeries are performed around the globe annually, using either a patient's own tissue (autografts) or cadaver tissue (allografts). Prior attempts at use of animal tissue or synthetic grafts to meet the high demands of the knee have proven unsuccessful. The Z-Lig™ provides a revolutionary new option for patients around the world. Aperion's device is designed to provide immediate stability and function to the knee while promoting gradual remodeling into human tissue over time.

“The international trial and CE Mark approval independently confirm the successful results we saw in our US pilot study which now has patients with Z-Lig™ devices 10 years after implantation,” says Kevin R. Stone, M.D., the founder of Aperion Biologics. “The advantage of an off-the-shelf, biologic device is it avoids the weakening of the patient by taking their own tissue.” (Dr. Stone was not a participant in the CE Mark trial).

### *About Aperion Biologics, Inc.*

Aperion Biologics, Inc., located in San Antonio, Texas, is a privately owned, medical device company addressing the need for alternatives to human-based grafts with animal-based tissue technology. Aperion developed and patented a technique to make animal tissues compatible for challenging human applications. The core platform technology utilizes the Company's proprietary Z-Process™, which removes the key antigens from animal tissues, followed by a conversion process that both stabilizes and sterilizes the tissue without affecting its biomechanical or biological properties. This creates functioning scaffolds capable of remodeling into healthy tissue. Aperion's Z-Process™ is applicable to a variety of tissues used in orthopaedic, cardiovascular, plastic, general and other surgical specialties. The Z-Lig™ ACLR Device is approved for revision and multiligament ACL procedures in the EU, and Aperion now has the opportunity to pursue markets recognizing the CE Mark. Currently, the device is not commercially approved for sale in the United States or other markets.

For more information, please contact:

Daniel R. Lee  
Chief Executive Officer  
Aperion Biologics, Inc.  
Phone: 210.858.7070  
dlee@aperionbiologics.com  
www.aperionbiologics.com