



JMEA Passes FDA Inspection with Flying Colors

ROCKVILLE, MD, December 12, 2011 (JMEA Corporation) – JMEA Corporation was issued a “Notice of Inspection” (FDA 482) on October 5, 2011. The inspection was concluded on October 12, 2011. JMEA was found in compliance with the current FDA Regulations. An FDA 483 (Inspectional Observations) was not issued. No warnings or deficiencies were issued. On November 7, 2011 an Establishment Inspection Report (EIR) was issued confirming the results of the inspection.

These are periodic, mandatory inspections performed by the United States Food and Drug Administration (FDA) of all registered medical device manufacturers and specification developers. The product covered was the Edison[®] ACL Screw Set. This was JMEA’s first inspection.

The JMEA Facility underwent a comprehensive Quality System Regulation inspection. A complete Good Manufacturing Process (GMP) Inspection was performed. The following systems were covered during the inspection: Management Controls, Design Controls, Corrective and Preventative Actions (CAPA), and Production & Process Controls. Some of the key records reviewed included: policies and procedures, device master record (DMR), and design history file (DHF).

“My congratulations to the entire JMEA staff and in particular to the Regulatory and Compliance staff for a job well done. JMEA is focused on quality and the results of the FDA inspection demonstrate our commitment. In our industry it is rare to go through such an inspection and not get any deficiencies. This is a significant achievement,” said Jack Yeh, President and CEO of JMEA.

About JMEA

JMEA is an emerging medical device company focused on the development and commercialization of orthopedic implants. JMEA is developing proprietary technologies along with an innovative business model. Currently, JMEA has patents issued in spinal and sports medicine technology, as well as patent applications filed and pending in the spine, sports medicine, joint replacement and bone fixation technology areas. JMEA sells and markets the Edison[®] ACL Screw Set for ACL/PCL reconstruction.