COOK®

Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, IN 47906
Phone: 765-497-3355
Toll Free: 888 299-4224
Fax: 765-497-2361
www.cookbiotech.com

CERTIFICATE OF COMPLIANCE

As the authorized Management Representative for Cook Biotech Incorporated, I certify the following:

Cook Biotech is a member of the Cook Group of Bloomington, Indiana and is an FDA registered medical device manufacturer regulated under the Quality System Regulations (QSR) 21 CFR 820. Our registration number is 1835959. Cook Biotech was last inspected by the FDA, March 03-08, 2008. No deficiencies were noted and no Form 483 was issued.

Cook Biotech is also certified by The German Notified Body TÜV as compliant to the European Union requirements per ISO 13485. Our certificate number is S 951 03 1756 and is valid through 22 Feb 2012. We are also certified by TÜV to meet the Canadian Medical Device requirements. The last TÜV inspection was in January 2010.

All products marketed in the U.S. have received FDA 510(k) clearance. All products marketed in other countries have received approval from the appropriate governing bodies.

All animals are sourced in the United States. Farms are inspected annually by Cook Biotech and by a veterinarian. Animals are raised in conditions compliant with EN ISO 22442.

All CBI products are derived from porcine small intestine submucosa (SIS). SIS is an acellular, collagen matrix. As such, all Cook Biotech products are exempt from FDA regulations (21 CFR parts 1270-1271) HUMAN CELLS, TISSUES AND CELLULAR AND TISSUE BASED PRODUCTS per 21 CFR 1271.3(d)(6).

On 01 July 2005, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) tissue standards went into effect for any JCAHO accredited organization that stores or implants allograft or human tissue. As an acellular, collagen matrix derived from porcine small intestine submucosa (SIS), Cook Biotech products are also exempt from these standards. SIS products are exempt from JCAHO requirements per rules published in the Comprehensive Accreditation manual for Hospitals: The Official Handbook, Refreshed Core, January 2010, Transplant Safety, page TS-7, Introduction to Standards TS.03.01.01, TS.03.02.01, and TS.03.03.01 states as follows: "The following standards apply to hospitals that store or issue tissue...Collagen and tissue products derived from plastics and polymers are not evaluated under these standards", thus JCAHO tissue storage and tracking regulation do not apply to CBI products.

On 17 November 2006 the FDA issued a new document to detail tracking requirements for medical devices. Under these rules, tracking is required only when the FDA issues a Tracking Order. No Tracking orders have ever been issued for any Cook Biotech product. In short, no tracking requirements have ever been applicable to any CBI product under any of the JCAHO, FDA or international regulations, current or previous.

Perry W. Guinn

15 Mar 2010

Perry W. Guinn
Vice President, Quality Assurance & Regulatory Affairs
Cook Biotech Incorporated

Date