COOK BIOTECH INCORPORATED
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CERTIFICATE OF COMPLIANCE

As Vice President of Quality and Regulatory Affairs, and as an Officer of 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 is also certified by the German Notified Body TUV as compliant to the European Union requirements per ISO 13485 and MDSAP. We are also certified by TUV to meet the United States (FDA), Canadian (HC), Brazilian (ANVISA), Australian (TGA) and Japanese (MLHW) requirements. The last TUV inspection was from 05 November through 07 November 2019.

All SIS 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 under conditions compliant with EN ISO 22442.

All CBI products derived from porcine small intestinal submucosa (SIS), a sterile acellular, collagen matrix, 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 17 November 2006 the FDA issued a document to detail tracking requirements for medical devices. Under the new 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.**

On 26 October 2010, the Joint Commission on Accreditation of Healthcare Organization (JCAHO) issued a letter regarding Cook Biotech Incorporated SIS products and stated "[Cook Biotech SIS products] are not subject to the Joint Commission Tissue Storage and Issuance Standards."

Perry W Guinn 23 MAR 2020

Perry W. Guinn

Vice President of Quality and Regulatory Affairs

rev 23 March 2020

The Joint Commission

October 26, 2010

Joan S. Antokol
Managing Partner
Park Legal, LLC
8910 Purdue Rd., Suite 480
Indianapolis, IN 46268

Dear Ms. Antokol,

Thank you for your recent inquiry regarding the applicability of The Joint Commission's Tissue Storage and Issuance standards (TS) to the SIS products manufactured by Cook Biotech.

As background information, the Tissue Storage and Issuance standards are intended to support healthcare organizations with the development and implementation of procedures for managing the potential transmission of infectious disease associated with the use of tissue products. The introduction published in our accreditation manual for standards TS.03.01.01 – TS.03.03.01 states the Tissue Storage and Issuance standards "apply to human and nonhuman cellular-based transplantable and implantable products whether classified by the U.S. Food and Drug Administration (FDA) as a tissue or a medical device." Manufacturer instructions commonly note the risks associated with the use of tissue and cellular based products and their potential to transmit infectious disease. For this reason, the Joint Commission TS standards specifically apply to biologics which contain cellular elements at the time of implant.

As the SIS products manufactured by Cook Biotech are rendered acellular at the time of use for the patient and the manufacturing process significantly reduces the potential risk of transmission of an infectious disease, they are not subject to the Joint Commission's Tissue Storage and Issuance standards.

The Joint Commission encourages healthcare organizations to review the Tissue Storage and Issuance standards and consider if it is beneficial to have similar procedures in place for medical devices. The essential themes of the Tissue Storage and Issuance standards are similar to those required of healthcare organizations for other compliance activities, such as those related to managing medications and blood products. These essential themes are: 1) Oversight, 2) Standardized procedures, 3) Tracking and 4) Adverse event investigation. While acellular medical devices are not subject to the same stringent Joint Commission standards for tracking documentation as are applicable to tissue products, some level of tracking and management is required by the FDA in the event of a recall. In recognition of this broader implication, some tissue tracking software vendors include medical devices in the design of their systems.

The Joint Commission

The Joint Commission has no specific plans to require additional record keeping for medical devices now or in the future. However, it is important to note that the evolution of the electronic medical record and integrated record keeping databases will enable healthcare organizations to maintain more detailed documentation, possibly influencing the FDA's oversight abilities and requirements.

Please let me know if I can be of further assistance.

Sincerely,

Megan E. Sawchuk

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