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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1912-2023

Biological evaluation and testing of medical devices for soft tissue regeneration

用于软组织再生医疗器械的生物学评价与试验

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1.Structure and Drafting Rules of Standardization Documents" Drafting. Please note that some content in this document may be subject to patents. The publisher of this document assumes no responsibility for identifying patents. This document is proposed by the National Medical Products Administration. This document is under the jurisdiction of the National Standardization Technical Committee for Biological Evaluation of Medical Devices (SAC/TC248). This document was drafted by: Shandong Medical Device and Drug Packaging Inspection Institute, Shanghai Songli Biotechnology Co., Ltd., National Pharmaceutical Medical Device Technical Review Center of the Supervision and Administration Bureau, Sichuan University, Peking University Shenzhen Research Institute, Chongqing Drug Technical Review and Inspection Center, Beijing JINGBANGSE TECHNOLOGY CO., LTD. The main drafters of this document. Shi Yanping, Liu Chenghu, He Hongbing, Liu Wenbo, Zhang Kai, Xi Tingfei, Guo Qi, Lin Hai, Lai Chen, Nie Hongtao, Gao Lihong, Wang Xuan.

Soft tissue regenerative medical devices are a class of medical devices composed of new biomaterials with unique physical, chemical and biological properties. Devices [such as the newly added subcategory "Tissue-induced implantable devices" (13-11-04)] in the "Medical Device Classification Catalog" generally have the ability to generate Degradation products that are non-toxic and easily metabolized by the body, and have degradation properties that match the regeneration of body tissue, etc. The types of constituent materials include the same or different A variety of biological materials and synthetic materials, etc. Common products include peripheral nerve repair implants, artificial corneal matrix, acellular conjunctival matrix, hernia repair Repair patches, anastomotic reinforcement patches, dura (spinal) membrane patches and anal fistula repair patches, etc. In view of the unique characteristics of soft tissue regeneration medical devices, point, when conducting biological evaluation and testing, the methods of GB/T 16886 (all parts) may have situations that have not yet been covered. therefore, Based on the characteristics of soft tissue regeneration medical device products, this document provides guidelines for biological

evaluation and testing based on risk management. guide. For soft tissue regeneration medical devices Biological evaluation and testing

1 Scope

YY/T 1912 covers the biological evaluation of devices intended for soft tissue regeneration, the scaffolds, matrices and fillers meant to be colonised and remodelled rather than to sit inert. The standard biocompatibility framework asks whether a material harms the body; a regenerative device raises the further question of whether the body responds to it in the way the product claims. This document sets out the evaluation and the tests that address that, covering the local tissue response over time, the degradation of the material and the tissue that replaces it. Soft tissue regeneration products are a fast-moving Chinese sector spanning wound care, dermal fillers and surgical repair. For a developer, this is the evaluation framework a Chinese registration dossier is expected to follow.

This document describes biological evaluation and testing methods for soft tissue regenerative medical devices. This document is applicable to the biological evaluation of soft tissue regeneration medical devices based on GB/T (Z) 16886.

2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, the dated quotations For undated referenced documents, only the version corresponding to that date applies to this document; for undated referenced documents, the latest version (including all amendments) applies to this document.

GB/T 16886.1 Biological evaluation of medical devices Part

3 Terms and definitions

The terms and definitions defined in GB/T 16886.1 and the following apply to this document.

3.1 soft tissue Relative to hard tissues such as bones, tissue that connects, supports, or surrounds other structures and organs of the body.

Note. Soft tissues include tendons, ligaments, fascia, skin, fibrous tissue, fat, and sarcolemma (i.e., connective tissue) as well as muscles, nerves, and blood vessels (not connective tissue). Weaving) etc. [Source: ASTMF3515-21,3.1.5, modified]

3.2 regeneration The replacement, restoration or growth of new functional tissue for tissue failure due to aging or disease, or due to injury or congenital defects. Loss of tissue caused by collapse.

3.3 tissue regenerationtissueregeneration Through their migration, differentiation and

proliferation, cells deposit extracellular matrix with normal structure, function and appearance to replace the healing of damaged tissue. combination process. [Source: ASTMF3163-22,3.3.7]

3.4 scaffoldscaffold Biomaterial structures used as matrices and guides for tissue repair and regeneration.

3.5 A cell-free scaffold formed by removing cells from the extracellular matrix through biological, chemical and/or physical treatment. [Source: ASTMF3163-22, 3.5.18, modified]