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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1754.3-2023

Preclinical animal studies of medical devices - Part 3: Animal abdominal wall incision model for evaluating the histological response and biomechanical performance of surgical mesh

医疗器械临床前动物研究 第3部分：用于评价补片组织学反应与生物力学性能的动物腹壁切口模型

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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. This document is Part 3 of YY/T 1754 "Preclinical Animal Studies of Medical Devices". YY/T 1754 has released the following parts.

1.General requirements;

2.Induced diabetic rat skin defect model;

3.Animal abdominal wall incisional hernia model used to evaluate the histological response and biomechanical properties of the patch. 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 Institute of Medical Device and Drug Packaging Inspection, Shanghai Changzheng Hospital, University of Shanghai for Science and Technology, Jiangsu Kebiao MEDICAL TESTING LIMITED. The main drafters of this document. Liu Chenghu, Hou Li, Zhang Jian, Sun Wenquan, Zhang Qi, Lin Zhenhua, Zhou Yangfei, and Zhu Fuyu.

YY/T 1754 aims to establish specific test methods for preclinical animal research on medical devices and is intended to consist of three parts.

1.General requirements. The purpose is to provide general requirements for preclinical animal studies of medical devices.

2.Induced skin defect model in diabetic rats. The purpose is to provide the structure of skin defect model in induced diabetic rats. construction method.

3.Animal abdominal wall incisional hernia model used to evaluate the histological response and biomechanical properties of the patch. The purpose is to give Testing and evaluation methods for the histological response and biomechanical properties of intra-abdominal patches. Medical Device Preclinical Animal Studies Part 3. Used to evaluate the histological response and biomechanics of the patch Performance of the Animal Abdominal Wall Incisional Hernia Model

1 Scope

YY/T 1754.3 specifies the animal model used to evaluate surgical mesh before it reaches patients: an abdominal wall incision repaired with the mesh under test, examined afterwards for how the tissue responded and how strong the repair became. It sets out the model itself, how the mesh is implanted, the time points, and how the histological response and the biomechanical performance are measured, so that results from different meshes and different laboratories can be compared. Hernia mesh has been the subject of large-scale litigation internationally over adhesion, contraction and chronic pain, all of which are tissue-response problems this model is designed to surface early. For a manufacturer of surgical mesh seeking Chinese registration, this is the preclinical protocol a reviewer expects.

This document describes methods for testing and evaluating the histological response and biomechanical properties of intra-abdominal prostheses. This document is applicable to preclinical animal testing studies of intra-abdominal mesh.

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 16886.2 Biological evaluation of medical devices Part

3 Terms and definitions

The terms and definitions defined in GB/T 16886.2 and the following apply to this document.

3.1 hernia The internal organs or tissues leave their normal anatomical parts and enter another place through weak points, defects or pores formed by nature or acquired. parts.

3.2 incisional hernia Hernia at the site of surgical incision.

Note. Generally seen after abdominal surgery, the deep fascial layer is split or not healed,

causing the internal organs or tissues to protrude into the normal abdominal wall under the action of intra-abdominal pressure. outside the layer plane.

4 Animal choices

Experimental animals of qualified quality should be used. It is advisable to fully consider the anatomical structure of the abdominal wall and the degree of neoperitonealization between animals and humans. of comparability. It is recommended to use healthy non-pregnant experimental pigs, whose weight is generally not less than 40kg. If other species of animals are selected, their suitability should be Be explained. The number of animals should be selected based on factors such as the purpose of the experiment, design type, evaluation indicators and accuracy of evaluation methods, as well as statistical factors. Let's consider it comprehensively. It is recommended that the animal sample size of the test sample group and the control sample group that completes the effective test at the final observation point is not less than 10.

5 Main instruments and equipment

Commonly used surgical instruments, animal anesthesia monitoring equipment, laparoscopy (optional), universal tensile machine, pathological examination equipment, etc.