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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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Preparation and evaluation methods of histopathological samples after implantation of absorbable medical devices

可吸收医疗器械植入后组织病理学样本制备与评价方法

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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 Institute of Medical Device and Drug Packaging Inspection, Peking University Stomatological Hospital, Shanghai Jiao Tong University School of Medicine The Affiliated Ninth People's Hospital and Tianjin Medical Device Quality Supervision and Inspection Center. The main drafters of this document. Liu Jia, Sun Likui, Han Jianmin, Sui Baiyan, Yuan Bo, Ren Xinxin, Sun Jiao, Che Guoxi, and Sun Xiaoxia.

The evaluation of local reactions and degradation after implantation of absorbable medical devices is different from that of non-absorbable medical devices, which are reproducible and meaningful. The evaluation history is not very long. Absorbable medical devices may not form fibrous cysts after implantation, but material degradation and phagocytic degradation products may occur. cells of things. When evaluating, consider whether the absorbable medical device degrades at the implantation site, and the impact of the implant itself and degradation products on local tissues. inflammatory response and the impact on the repair process at the implant site. For resorbable bone implants, in addition to the degradation performance, the evaluation also includes the implant periphery Peripheral new bone formation. Imaging techniques, radiopaque marking or surgical observation as long as they do not compromise animal welfare or interfere with expected biological responses All other methods are feasible. Histopathological samples after implantation of absorbable medical devices Preparation and evaluation methods

1 Scope

YY/T 1899 sets out how histopathology samples are prepared and read after an absorbable device has been implanted. An absorbable implant is meant to disappear, and the question a reviewer asks is what the tissue looks like while it does: how the material degrades, how the surrounding tissue responds at each stage, and what is left behind at the end. Ordinary histology protocols struggle with these specimens, because the implant is disintegrating and can be lost, distorted or mistaken for artefact during processing. This document fixes the sectioning, staining and evaluation so that findings at different time points and from different laboratories can be compared. For a manufacturer of absorbable sutures, screws, stents or scaffolds, this is the method the degradation and local-effect evidence in a Chinese dossier is expected to follow.

This document describes the preparation of local histopathological specimens and evaluation of tissue response and degradation after implantation of absorbable medical devices. method. This document applies to absorbable medical devices.

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 16886.6 Biological evaluation of medical devices Part

3 Terms and definitions

The terms and definitions defined in GB/T 16886.6 apply to this document.

4 Histopathological sample preparation methods

4.1 General In the preparation of histopathological specimens for local reactions after implantation of absorbable medical devices, the tissue envelope is in contact with the fixative before or after contact. They may all be open. Care should be taken to avoid damaging the implant/tissue interface. The implant should be completely embedded with the tissue in situ and recorded. Condition of the implant surface and tissue interface. For "hard" implants (absorbable artificial bone, absorbable metal, absorbable polymer, etc.), you can Histopathological sections are prepared using resin embedding and appropriate sectioning or grinding techniques without decalcification. Avoid using dissolves during the process The solvent of the material (for example, some absorbable gel products may be dissolved in fixative, dehydrating clear solution, staining solution, and mounting solution), if

it cannot be avoided To avoid this, steps should be taken to mark the location of the material in the organization.

4.2 Collection of implant-containing tissue samples For local reaction tests after implantation of absorbable medical devices, when taking samples at the specified time, identification of implantation site markers (such as Non-invasive permanent skin dye, non-absorbable sutures, etc.) to determine implant location. In the early stage of implantation of absorbable medical devices, the sample may not degrade or degrade slightly. In the mid-term, substantial structural disorder and/or device may occur. Mechanical fragmentation, try to be as complete as possible when extracting materials. In the later stages of degradation, the absorbable implant may be basically absorbed, and the extraction site is not obvious, so it needs to be expanded and removed. Site, including tissue 2mm~5mm around the intended implantation site, including any identifiable residual material as much as possible, and drainage if necessary Lymph nodes, as well as immune organs such as spleen and thymus.

4.3 Fixed Fixation can maintain the inherent shape and structure of cells and tissues, harden the tissues, and facilitate cutting. When fixing, use appropriate fixative