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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0606.10-2008

Tissue engineered medical products - Part 10: Guide for in vivo assessment of implants for repair or regeneration of articular cartilage

组织工程医疗产品 第10部分：修复或再生关节软骨的植入物体内评价指南

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Foreword

YY/T 0606 "tissue-engineered medical products" is divided into.

--- Part 1. General requirements;

--- Part 3. General classification;

--- Part 4. skin product classification;

--- Part 5. Matrix and stent performance and testing;

--- Part 6. I collagen;

--- Part 7. chitosan;

--- Part 8. sodium alginate;

--- Part 9. hyaluronic acid;

--- Part 10. implanted in the body to repair or regenerate cartilage evaluation guidelines;

--- Part 12. cell, tissue, organ processing;

--- Part 13. automatic cell counting method. This section YY/T Part of 100,606. This part is proposed by the State Food and Drug Administration. This part of the jurisdiction of the State Food and Drug Administration seized the Medical Device Quality Supervision and Inspection Center. This in part by the Chinese Pharmaceutical and Biological Products, Zhejiang University drafted. The main drafters of this section. Chen Liang, Ouyang magnificent, Xi Tingfei, Wang Chunren. Tissue-engineered medical products - Part 10. Repair or Regeneration of articular cartilage implanted into the body evaluation guidelines

1 Scope

YY/T 0606.10 is Part 10 of the Chinese tissue engineered medical product series and guides the in vivo assessment of implants intended to repair or regenerate articular cartilage. Cartilage is the tissue that does not heal itself, which is why it has attracted so many engineered solutions and why evaluating them is hard: the endpoint is whether durable hyaline cartilage forms rather than fibrocartilage, and that can only be judged in an

animal model over time, with defined defect creation, follow-up and histological scoring. This guide fixes that study design. It is the in vivo counterpart of YY/T 1995, which covers the in vitro cell response to cartilage scaffolds. For a manufacturer developing cartilage repair implants for China, this is the reference the animal evidence follows.

YY/T 0606 provisions of this part of the repair or regeneration of articular cartilage implanted in the body of General Evaluation. This section of the implant Biological material may be natural or synthetic (biocompatible and biodegradable), or a composite structure, can comprise cells, drugs, or growth Factor, synthetic polypeptides, cDNA plasmid or other bioactive factors. This section describes the rabbits, dogs, pigs, goats, sheep and other animal models of different species of the genus and the corresponding test procedures, as well as morphology, tissue-ingrowth The results of measurement and evaluation methods were chemical and biomechanical analysis.

2 Normative references

The following documents contain provisions which, through reference

YY/T 0606 and become part of the provisions of this section. For dated references, All subsequent amendments (not including errata content) or revisions do not apply to this section, however, encourage the agreement on this section Whether the parties can study the latest versions of these documents. For undated reference documents, the latest versions apply to this section.

GB/T 16886.1-2001 Biological evaluation of medical devices - Part 1. Evaluation and testing (idt ISO 10993-1.1997)

3 Terms and Definitions

The following terms and definitions apply YY/T 0606 to the present section.

3.1 Natural cartilage has a similar morphology, biochemistry and tissue formation biomechanical properties of articular cartilage samples.

3.2 Damaged cartilage or a substitute by cell proliferation and extracellular matrix synthesis of new healing process.

3.3 Cartilage matrix contains a large number of parallel or interwoven arrangement of collagen fibers, the chemical composition of cartilage collagen type I, no fixed Few shaped matrix, chondrocytes often distributed in rows between the fiber bundle.

3.4 Located on the surface of the articular cartilage, the main component of cartilage matrix proteoglycans and water, the fibers are made of plastic consisting of collagen type II Protofibrils, cartilage chondrocytes located lacuna. 4. Significance and Use Objective

4.1 section is to provide a variety of animal models for clinical repair or regeneration of

articular cartilage tissue engineered medical products Before evaluation.

4.2 part comprises animal model introduction, operation points, as well as organizations dealing with qualitative and quantitative analysis of tissue samples and the like. Users should be in accordance with section

4.3 GB/T 16886.1 Biological Evaluation of Medical Devices standards, making this part of the body Before evaluation, material and cytotoxicity and biocompatibility tests/or instruments.