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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0919-2014

Non-active surgical implants - Joint replacement implants - Specific requirements for knee-joint replacement implants

无源外科植入物 关节置换植入物 膝关节置换植入物的专用要求

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Foreword

This standard was drafted in accordance with GB/T 1.1-2009 given rules. This standard uses the translation method identical with ISO 21536.2007 "active surgical implants - Joint replacement implants implanted knee replacement Requirements for the material. " This standard and ISO 21536.2007 as compared to only normative references have been adjusted to technical differences, in order to adapt to China Technical conditions, the consistency of the correspondence between the standard international documents and normative references of the following documents. YY/T 0640-2008 active surgical implants General requirements (ISO 14630.2005, IDT) YY/T 0810.1-2010 surgical implant a total knee prosthesis - Part 1. Determination of fatigue properties of the tibial tray (ISO 14879-1.2000, IDT) Please note that some of the content of this document may involve patents. Release mechanism of the present document does not assume responsibility for the identification of these patents. This standard was proposed by the China Food and Drug Administration. This standard by the national surgical implants and orthopedic instruments Standardization Technical Committee materials and orthopedic implants Technical Committee (SAC / TC110/SC1) centralized. This standard was drafted. China Medical Device Industry Association of Professional Committee of surgical implants, the State Food and Drug Administration, Tianjin Medical Therapy Devices Quality Supervision and Inspection Center, Beijing Air Materiel Biam tech Co., Ltd., a Johnson Medical Devices (China) Co., Ltd. The main drafters of this standard. Sun Jianwen, Yao Zhi repair, Zhang said, Dongshuang Peng, Liang Fanghui, Zhouxue Yu, Cheng Hongyuan.

Standard relates to active surgical implants and related instruments are divided into three levels, involving the implant itself standard grades are as follows (a Standards for the highest).

--- One. General requirements for passive surgical implants;

--- Class 2. Particular requirements for various types of active surgical implants;

--- Three levels. active surgical implants for a variety of special requirements. The standard for the three standards, including a dedicated knee replacement implant requirements. A standard YY/T 0640 contains apply to all active surgical implant requirements, but also prompt in the secondary and tertiary standards There are some additional requirements.

Secondary standard applies to more limited class of active surgical implants, such as those designed for osteosynthesis, cardiovascular surgery, or joint home In other implants. To understand all the requirements, should the current minimum level of standard inspection began. Active surgical implants - Joint replacement implants Knee replacement implant-specific requirements

1 Scope

YY/T 0919 is the Chinese standard that gathers what is specifically required of a knee replacement implant, as opposed to joint replacement implants in general. It specifies the intended performance of such an implant, its design attributes, the materials it may be made from, how the design is evaluated, and the manufacturing, sterilization, packaging and information requirements that accompany it. It is the document that turns the general framework for non-active surgical implants into something a knee prosthesis can actually be assessed against, and it is where a Chinese reviewer looks for the design rationale in a registration dossier. The standard carries Amendment 1 of 2023. For an orthopaedic manufacturer it sits alongside the YY/T 1426 wear-testing series, which supplies the durability evidence this standard expects.

This standard specifies the knee replacement implant-specific requirements. General safety, this standard specifies the expected performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and manufacturers Information, as well as the requirements, test methods.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein Member. For undated references, the latest edition (including any amendments) applies to this document.

YY/T 0640-2008 active surgical implants General requirements (ISO 14630.2005, IDT)

YY/T 0810.1 surgical implant a total knee prosthesis - Part 1. Fatigue properties of knee tibial tray Determination (YY/T 0810.1-2010, ISO 14879-1.2000, IDT)

YY/T 0924.1 Implants and total knee prosthetic components - Part 1. Classification, definitions and dimensions (YY/T 0924.1-2014, ISO 7207-1.2007, MOD) ISO 14243-

1 Implants for surgery - Wear of total knee prostheses - Part 1. load control load and wear tester position Shift parameters and the corresponding environmental conditions for test (Implantsforsurgey-Wearoftotalknee-jointprostheses-Part 1. Loadinganddisplacementparametersforwear-testingmachineswithloadcontrolandcorresponding enviromentconditionsfortest) ISO 14243-

2 Implants for surgery - Wear of total knee prostheses - Part 2. Methods of measurement

(Implantsforsurgey- Wearoftotalknee-jointprostheses-Part 2. Methodsofmeasurement) ISO 14243-

3 Implants for surgery - Wear of total knee prosthesis Part 3. displacement control load and wear tester position Shift parameters and the corresponding environmental conditions for test (Implantsforsurgey-Wearoftotalknee-jointprostheses-Part 3. Loadinganddisplacementparametersforwear-testingmachineswithdisplacementcontrolandcorre- spondingenvironmentalconditionsfortest)

ISO 21534.2007 active surgical implants - Joint replacement implants - Particular requirements (Non-activesurgery-Jointre- placementimplants-Particularrequirements)

3 Terms and Definitions

ISO 21534 and YY/T 0924.1 and the definition of the following definitions apply to this document.

3.1 Femoral component femoralcomponent For fixing on the femur and total knee replacement articular surface replacement parts. NOTE. These implants may be manufactured in one piece or set of components assembled by the user.