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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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YY/T 0964-2014

Implants for surgery - Bioglass and glass ceramic biomaterials

外科植入物 生物玻璃和玻璃陶瓷材料

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Foreword

This standard was drafted in accordance with GB/T 1.1-2009 given rules. The standard reference ASTMF1538-03 "surgical implants bioactive glass and glass-ceramic materials," this standard and ASTMF1538-

03 The main difference is that. This standard uses the applicable national standards or industry standards instead of ASTM standards; increasing the biological activity of the test material method. 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. Shanghai Institute of Ceramics, Chinese Academy of Sciences, Tianjin Medical Device Quality Supervision and Inspection Center. The main drafters of this standard. Lin Kaili, Chang Jiang, Ma Chun Bao, makin bamboo, Li Libin. Surgical implants bioactive glass and glass-ceramic material

1 Scope

YY/T 0964 is the material standard for bioglass and glass ceramic biomaterials used in surgical implants. These are the bioactive materials that bond chemically to bone rather than merely sitting against it, used as bone graft substitutes, coatings and in dental and maxillofacial reconstruction. Their behaviour is governed by composition and by the surface reaction that forms an apatite layer in body fluid, so the standard has to control chemistry, phase composition and the physical properties that follow from them. It cites an extensive set of normative references, reflecting how much of the biological evaluation is inherited from the general implant standards. For a manufacturer of bioactive glass products or a supplier serving them in China, this is the material specification.

This standard specifies the surgical implant with bioactive glass and glass ceramic materials requirements and testing technology, the material can be used in the present standard Porous and powdered surgical implants, can also be used to coat surgical instruments, but does not include a drug delivery system. Bioactive glass and glass

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ceramics Biological response and bone and soft tissue has been proven in laboratory studies and clinical applications. This standard does not contain the tricalcium synthetic hydroxyapatite, hydroxyapatite coating, alumina ceramic, alpha- and beta- tricalcium phosphate and white phosphorus Calcium stone.

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.

GB/T 1347 soda-lime-silica glass chemical analysis

GB/T 5432 glass densitometry buoyancy method

GB/T 6040 General rules for infrared spectroscopy Gravity measurements

GB/T 6524 metal powder particle size distribution sedimentation light transmission method

GB/T 6609.35 alumina chemical analysis methods and determination of physical performance - Part 35. Determination of nitrogen than the surface area of absorption Attached law

GB/T 14901 glass densitometry ups and downs of Comparative Law

GB/T 16534 Test method for hardness of fine ceramics at room temperature

GB/T 16535 Fine Ceramics linear thermal expansion coefficient Test Method ram method (GB/T 16535-2008, ISO 17562.2001, MOD)

GB/T 16886.1 Biological evaluation of medical devices - Part 1. Evaluation and testing

GB/T 19077.1 laser diffraction particle size analysis - Part 1. General (GB/T 19077.1-2008,

ISO 13320-1. 1999, IDT) Section 4

GB 23101.4 surgical implants hydroxyapatite. Determination of coating adhesion strength (GB 23101.4-2008,

ISO 13779-4.2002.IDT) People's Republic of China Pharmacopoeia (two) Strength test methods JC/T 676 curved glass JC/T 678 glass material elastic modulus, shear modulus and Poisson's ratio test method JY/T 009 rotating anode X-ray diffraction of polycrystalline General QB/T 3572 Methods for chemical analysis of borosilicate glass ASTMC633 thermal spray coating adhesion or bonding strength test method (TestMethodforAdhesionorCohesion StrengthofThermalSprayCoatings)

3 Terms and Definitions

The following terms and definitions apply to this document.

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