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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1305-2015

Clinical trial guideline for titanium and titanium alloy dental implants

钛及钛合金牙种植体临床试验指南

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Foreword

This standard was drafted in accordance with GB/T 1.1-2009 given rules. Please note that some of the content of this document may involve patents. Distribution of this document Institutions do not assume the responsibility to identify these patents. This standard was proposed by the China Food and Drug Administration. This standard by the National Standardization Technical Committee materials and oral appliances and equipment (SAC/TC99) centralized. This standard is mainly drafted by: Peking University School of Stomatology. The main drafters of this standard. wildland, Hu Xiulian. Titanium and titanium dental implants in clinical trials Guidelines

1 Scope

YY/T 1305 is the clinical trial guideline for titanium and titanium alloy dental implants in China. Dental implants are one of the few device classes where clinical evidence is routinely required and where the endpoints are unusually long-dated: survival, marginal bone loss and soft tissue health measured over years rather than months. The guideline sets out how such a trial should be designed, conducted and reported for a Chinese submission, which matters as much to a foreign manufacturer bringing existing data as to a domestic one starting fresh, because a trial designed to a different convention may not answer the questions a Chinese reviewer asks. For anyone registering a titanium implant system in China, this is the reference the clinical section is built on.

This standard specifies requirements and methods of clinical trials dental implants. This standard applies to material titanium and titanium dental implants in clinical trials (not including surface coating of titanium implants and other planting materials body).

2 Terms and definitions

The following terms and definitions apply to this document.

2.1 Oral Implantology Mild adverse reactions mildadversereactionsofdentalimplant Planting

areas appear local allergic reaction, implant abutments damaged or broken, the central screw loose or broken, mucosal flap dehiscence, hematoma, dead Bone formation, swelling and pain.

2.2 Oral Implantology severe adverse reactions severeadversereactionsofdentalimplant After planting systemic allergic reactions, jaw fractures, nerve paresthesia, implant loosening, implant loss, damage or broken implants.

2.3 Exit dropout Due to the subjective views of the subjects participating in the trial stopped.

2.4 Termination termination Because the objective conditions change during the test result was forced to stop the test.

2.5 Special specifications implant specialtypeimplants Diameter of less than 3.25mm, or length less than 7mm, or more than 30 ° abutment implant.

3 Clinical trials required before

3.1 Test Material Dental implants and related accessories.

3.2.1 The inclusion criteria

3.2.1.1 General Where a patient dentition defect or missing. Aged 18 to 70 years old, male or female.

3.2.1.2 surgical indications 3.2.1.2.1 edentulous or defect claim implant rehabilitation.