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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 1901-2023

**Requirements and test methods for orthopaedic surgical
navigation equipment using robotic technology**

采用机器人技术的骨科手术导航设备要求及试验方法

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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 responsible unit for medical robot standardization technology. This document was drafted by: China Institute of Food and Drug Control, Medical Device Technical Review Center of the State Food and Drug Administration, Shanghai Municipal Medical Device Inspection

and Testing Institute, Beijing Jishuitan Hospital, Chinese People's Liberation Army General Hospital, Liaoning Provincial Medical Device Inspection and Testing Institute, Beijing Tianzhi Hang Medical Technology Co., Ltd., Medtronic (Shanghai) Management Co., Ltd., Gushengyuanhua Robot (Shenzhen) Co., Ltd., Huake Precision (Beijing) Beijing) Medical Technology Co., Ltd. The main drafters of this document. Meng Xiangfeng, Peng Liang, Zhang Lihai, Wang Jing, Hong Wei, Tian Wei, Zhang Longda, Wang Hao, Zhang Chao, Hao Ye, Han Xiaoguang, Jin Lukai, Xu Jin, Li Lu, Yan Tingfang, Liu Wenbo, Wang Chenxi, Li Shu, Li Jiage, and Li Jingli. Orthopedic surgery navigation device using robotic technology Requirements and test methods

1 Scope

YY/T 1901 covers robotic orthopaedic surgical navigation equipment, the systems that register a patient's anatomy to preoperative imaging and then guide or constrain a robotic arm during joint replacement or spinal fixation. It sets the requirements such a system has to meet and the test methods that verify them, covering the accuracy of registration and of the resulting placement, the tracking, the behaviour when line of sight or registration is lost, and the safety limits on the robotic motion. Accuracy claimed in millimetres is the entire selling proposition of these systems, so the method by which it is measured decides whether the claim means anything. Robotic orthopaedics is a priority area for Chinese manufacturers. This is the text a Chinese registration is assessed against.

This document specifies the technical requirements for orthopedic surgery navigation equipment using robotic technology (hereinafter referred to as "orthopedic surgery navigation equipment"). Corresponding test methods are described. This document applies to navigation equipment for orthopedic surgeries (such as joint replacement surgery, spine surgery, trauma orthopedics, etc.).

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 reference documents, only the version corresponding to the date applies to this document; for undated referenced documents, the new version (including all amendments) applies to this document. document.

GB/T 4340.1 Vickers hardness test of metallic materials Part

3 Terms and definitions

The terms and definitions defined in YY/T 1712-2021 and the following apply to this document.

3.1 It consists of a computer with relevant software, a tracking device, etc., which can track

surgical instruments, robotic arm positioning devices, or treatment objects, and Devices that provide real-time feedback through digital model visualization.

Note. For the schematic diagram, refer to A.1 in Appendix A. [Source: ASTM F2554-18, 3.2.7, modified]

3.2 reference element A tool applied to a surgical instrument, treatment object, positioning system, or other device to determine its position in three-dimensional space through a tracking device. Intermittent position and posture.

Note. Commonly used reference devices include treatment object reference devices (reference devices that are applied to treatment objects or other devices and allow tracking of the object), positioning Reference device (a reference device applied to a positioning system, imaging system or other device and allowing tracking of the object), tracking reference device (applied to the hand A reference device on a surgical instrument or implant that allows tracking of the object), etc. [Source: ASTM F2554-18, 3.2.8, modified]