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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1941-2024

Robotically-assisted laparoscopic surgical system

采用机器人技术的腹腔内窥镜手术系统

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part

1.Structure and drafting rules for standardization documents" Drafting. Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This document is proposed by the State Food and Drug Administration. This document is under the jurisdiction of the medical robot standardization technical authority. This document was drafted by: China Food and Drug Inspection Institute, National Medical Products Administration Medical Device Technical Evaluation Center, Shanghai Medical Device Inspection Institute, Liaoning Medical Device Inspection Institute, Sichuan Drug Inspection Institute (Sichuan Medical Device Inspection Center Center), Beijing Surui Robotics Co., Ltd., Tianjin University, Shanghai Microport Medical Robotics (Group) Co., Ltd., Intuitive Fosun Medical Medical Device Technology (Shanghai) Co., Ltd., Harbin Sizhe Rui Intelligent Medical Equipment Co., Ltd., Johnson & Johnson (Shanghai) Medical Devices

Co., Ltd. Shenzhen Kangnuo Siting Technology Co., Ltd., Ximeian Surgical Instruments Co., Ltd., Ruilong Nuofu (Shanghai) Medical Technology Co., Ltd., Guangdong Jiahuamei Certification Co., Ltd., Suzhou Kangduo Robotics Co., Ltd., Beijing Medical Device Inspection Institute, Chongqing Jinshan Medical Machine PEOPLE LIMITED. The main drafters of this document are. Meng Xiangfeng, Li Jingli, Jin Lukai, Zhang Longda, Yang Wenlong1), Hong Wei, Chen Min, Wang Zerui, Wang Gang, Liu Lili, He Chao, Xu Kai, Wang Wei, Gu Yi, Sun Xiao, Xing Yuan, Kuang Chao, Zhang Yang, Yang Chenxu, Wang Hao, Yang Wenlong2), Zhang Chao, Wang Liao. 1) Sichuan Provincial Institute of Drug Control (Sichuan Provincial Medical Device Testing Center). 2) Suzhou Kangduo Robotics Co., Ltd.

Since the application scope and technology of this field are still developing, the technical characteristics and test methods specified in this document can only be based on the existing New technologies and methods (such as single-port surgical systems) that are adopted after full consideration of risks should not be excluded from this document. In these cases, the contents of this document should be used as a helpful guide and reference, but should not be used as a mandatory specification. As new product technologies and methods mature, this document will also revise the requirements and methods. Laparoendoscopic surgery system using robotic technology

1 Scope

YY/T 1941 is the product standard for the robotic laparoscopic surgery system, the console-and-cart platform used for minimally invasive abdominal procedures. It specifies the technical requirements for laparoscopic surgical systems employing robotic technology and describes the corresponding test methods. It is the abdominal counterpart of YY/T 1994 for vascular intervention, in a family of Chinese standards that has grown quickly as domestic surgical robot makers have come to market against the established platforms. The requirements reach the instrument control, the imaging chain and the safety behaviour of a system where the surgeon is not touching the patient. For a manufacturer or an importer of robotic laparoscopic systems seeking Chinese registration, this is the standard the type test report follows.

This document specifies the technical requirements for laparoscopic surgical systems using robotic technology and describes the corresponding test methods. This document applies to laparoscopic surgical systems using robotics technology, as well as machines connected through interaction conditions and interface conditions. Robotic surgical instruments. This document does not apply to laparoscopic single-port surgical systems.

2 Normative references

The contents of the following documents constitute essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced

documents without a date, the latest version (including all amendments) applies to This document.

GB/T 4340.1 Vickers hardness test for metallic materials Part

3 Terms and definitions

The terms and definitions defined in GB 9706.1, YY/T 1712, YY/T 1686, YY 9706.277 and the following apply to this document.

3.1 A laparoscopic surgical device/system using robotic technology, which is expected to control robotic surgical instruments through master-slave operation and/or endoscope, while viewing through the endoscope.

Note. RALS usually includes a doctor's console, a patient surgical platform, an image processing platform, a three-dimensional laparoscopic endoscope (abbreviated as endoscope), and a robotic surgical instrument. Machinery, etc.

3.2 A mechanical structure used to capture or record operator's hand movements.

Note. Also called the master hand.