ICS 11.040.30
CCS C35

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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1929-2024

Breast biopsy and excision equipment

乳房活检与旋切设备

Issued on: February 7, 2024 **Implemented on: March 1, 2025**

Issued by: National Medical Products Administration

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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 provided by the National Technical Committee for Standardization of Medical Electrical Appliances, Medical Electronic Instruments Standardization Subcommittee (SAC/TC10/SC5) Centralized. This document was drafted by: Chongqing Xishan Technology Co., Ltd., Shanghai Institute of Medical Device Inspection, Chongqing Municipal Drug Technical Evaluation Inspection Center, Mammotome Medical Device Manufacturing (Shanghai) Co., Ltd., Bard Medical Technology (Shanghai) Co., Ltd., Shanghai Xiuneng Medical Device Co., Ltd. Limited company. The main drafters of this document are. Guo Yijun, Yu Yuanjun, Chen Lizhong, Xu Chao, Zheng Wenhao, Gu Lihua, Yue Xin, Jiang Xiaoqi, Zhang Yanqing, Chen Zhu, Sun Yunhui. Breast Biopsy and Atherectomy Equipment

1 Scope

YY/T 1929 is the product standard for breast biopsy and vacuum-assisted excision equipment together with its rotational cutting needles. It sets the terms and definitions for the equipment and the needles, and specifies the materials and requirements with the corresponding test methods. Vacuum-assisted breast biopsy takes a contiguous sample large enough for reliable histology through a single small incision, which is what has made

it the standard of care for indeterminate mammographic findings, and its performance depends on the cutting mechanism, the vacuum that draws tissue into the aperture, and sample integrity, since a crushed sample cannot be read. The 2024 edition takes effect on 20 July 2025. For a manufacturer or an importer of breast biopsy systems, this is the governing standard.

This document defines the terms and definitions for breast biopsy and excision equipment and excision needles, specifies materials, requirements, and describes the appropriate tests method. This document applies to breast biopsy and excision equipment.

2 Normative references

The contents of the following documents constitute the 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 1220-2007 Stainless steel bars

GB/T 2965 Titanium and titanium alloy bars

GB/T 4340.1 Vickers hardness test for metallic materials Part

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Powered by the mains, it provides the mechanical power and vacuum source required by the rotary cutting needle, and vacuum-assisted suction of breast lesion tissue is used to Medical electrical equipment that uses a rotary cutting needle to cut and obtain breast lesion tissue samples. The equipment generally consists of a host, a handle, a rotary cutting needle, and a foot switch. And vacuum accessories.

3.2 An instrument clamped on a handle or integrally formed with the handle for tissue surgery. It consists of an outer needle tube, an inner needle tube, a main body and a vacuum catheter. The handle outputs power to drive the driven structure in the main body to drive the inner needle tube to translate, swing or rotate.