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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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Medical device clinical evaluation - Terms and definitions

医疗器械临床评价 术语和定义

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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 institution does not bear responsibility for identifying patents. This document is proposed by the State Food and Drug Administration. This document is under the jurisdiction of the National Medical Device Clinical Evaluation Standardization Technical Authority. This document was drafted by: Medical Device Technical Review Center of the State Food and Drug Administration. The main drafters of this document. Liu Yinghui, Liu Lu, Cheng Weilu and Cui Xinyue. Medical Device Clinical Evaluation Terms and Definitions

1 Scope

YY/T 1930 fixes the vocabulary of medical device clinical evaluation in China. It specifies the terms and definitions related to the clinical evaluation of medical devices, including those used in the design, conduct, recording and reporting of device clinical trials. Clinical evaluation, equivalence, clinical data and clinical evidence are words that carry different weight in different regulatory systems, and a Chinese submission that borrows a European or American usage can be read as claiming something it did not intend. This document is the terminology base under YY/T 0297, the general quality requirements for device clinical investigation. For a manufacturer preparing a clinical evaluation report for China, or adapting one written for another market, this is the document that settles what each term means to the reviewer.

This document defines the terms and definitions involved in the clinical evaluation of medical devices, including the design, implementation, recording and reporting of clinical trials of medical devices. terms and definitions used in reporting, etc. This document applies to the clinical evaluation of medical devices. This document does not apply to in vitro diagnostic reagents.

2 Normative references

This document has no normative references.

3.1 Clinical evaluation

3.1.1 Safety When the product is used within its intended scope, the risks are acceptable compared with the benefits.

3.1.2 Adverse event; AE < Clinical Evaluation> Medical events that are adverse to patients/subjects, users, or other persons. NOTE. Adverse events include unfavorable medical occurrences that may be associated with a medical device in clinical experience.

3.1.3 Equivalent device A situation where a medical device of the same type is a medical device that is equivalent to the medical device undergoing clinical evaluation.

Note. Equivalent devices have the same scope of application as the declared product, and the similarity of technical features and/or biological characteristics makes the safety and clinical performance of the two devices comparable. and/or medical devices for which there is no clinically significant difference in effectiveness.

3.1.4 Comparative device A medical device selected by the registrant to have its clinical data used to support the clinical evaluation of the product being applied for.

3.1.5 Risk Management Apply management policies, processes and practices to analyze, assess, control and monitor risks.

3.1.6 Conformity assessment The applicant for registration shall systematically examine the evidence generated and its process in accordance with the requirements of the regulatory agency to determine whether the medical device complies with the safety Basic principles of safety and performance.