

Grafiken des Blog-Beitrages:

Klinische Bewertung/Medizinprodukte für chinesischen Markt

Prozess der klinischen Bewertungen in China

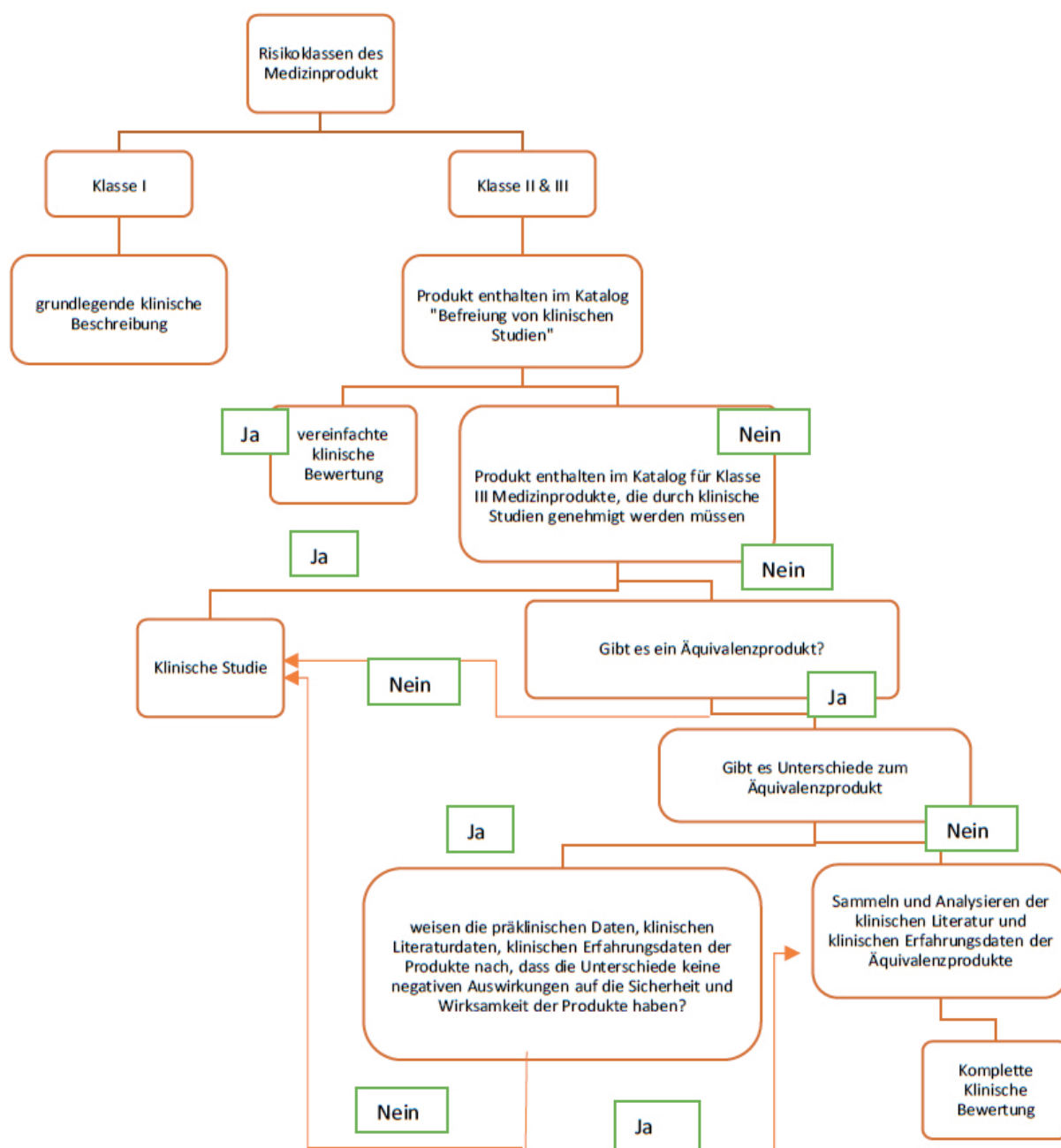


Figure 1 Prozess der klinischen Bewertung in China

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Vergleichstabelle von aktiven oder passiven Medizinprodukten

Passive Medical Devices	Active Medical Devices
Basic Principles	Basic Principles 1) Working Principles 2) Mechanism of Action
Structural Composition	Structural Composition 1) Product Composition 2) Core Components
Manufacturing Process	Manufacturing Process
Manufacturing materials (including material grades, animal-derived materials, allograft materials, ingredients, pharmaceutical ingredients, bioactive substances, and required standards, etc.)	Manufacturing materials in contact with human body (including material grades, animal-derived materials, allograft materials, ingredients, pharmaceutical ingredients, bioactive substances, and required standards, etc.)
Performance Requirement	Performance Requirement 1) Performance Parameters 2) Function Parameters
Safety Evaluation (e.g. biocompatibility, biological safety, etc.)	Safety evaluation (e.g. biocompatibility, biological safety, electrical safety, radiation safety, etc.)
Conformed National /Industry Standards	Software core Function
Range of application: 1) Target people 2) Target parts of body 3) Mode of contact with human body 4) Indications 5) Applicable stage and extent of diseases 6) Usage environment	Conformed National /Industry Standards
Application method	Range of application: 7) Target people 8) Target parts of body 9) Mode of contact with human body 10) Indications, Labeling 11) Applicable stage and extent of diseases 12) Usage environment
Contraindications	Application method
Precautions and Warnings	Contraindications
Delivery Status	Precautions and Warnings
Sterilization / Disinfection Methods	Sterilization / Disinfection Methods
Packaging	Packaging
Labeling	Labeling
Instruction for use	Instruction for use

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