



申报产品与同品种医疗器械的对比项目

(无源医疗器械)

Comparative table between product under approval and device with same variety

(non-active medical device)

	对比项目 compared items
无源 医 疗 器 械	1. 基本原理 fundamental principle
	2. 结构组成 structural composition
	3. 生产工艺 manufacturing technique
	4. 制造材料（如材料牌号、动物源性材料、同种异体材料、成分、 药物成分、生物活性物质、符合的标准等信息） Manufactural materials (such as material trademark, material of animal origin, allograft material, composition, ingredient, biological active substances, corresponding standard, etc.)
	5. 性能要求 performance requirements
	6. 安全性评价（如生物相容性、生物安全性） security evaluation (such as biocompatibility, bio-security, etc.)
	7. 产品符合的国家/行业标准 national/industrial standards
	8. 适用范围： applicable scope
Non- active medical device	<ul style="list-style-type: none"> (1) 适用人群 applicable population (2) 适用部位 applicable parts (3) 与人体接触方式 contact way with human body (4) 适应症 indications (5) 适用的疾病阶段和程度 applicable sickness stage and degree (6) 使用环境 environmental condition



9.使用方法
usage
10.禁忌症
contraindication
11.防范措施和警告
precautionary measure and warning
12.交付状态
delivery state
13.灭菌/消毒方式
sterilization/disinfection
14.包装
packaging
15.标签
labeling
16.产品说明书
manual instruction