

申报产品与同品种医疗器械的对比项目

(有源医疗器械)

Comparative table between product under approval and device with same variety

(active medical device)

有源 医 疗 器 械 active medical device	对比项目 compared items
	1. 基本原理 fundamental principle (1) 工作原理 operating principle (2) 作用机理 functional mechanism
	2. 结构组成 structural composition (1) 产品组成 product composition (2) 核心部件 core parts
	3. 生产工艺 manufacturing technique
	4. 与人体接触部分的制造材料 (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 of parts will contact human body (such as material trademark, material of animal origin, allograft material, composition, ingredient, biological active substances, corresponding standard and so on)
	5. 性能要求 performance requirements (1) 性能参数 performance parameter (2) 功能参数 functional parameter
	6. 安全性评价 (如生物相容性、生物安全性、电气安全性、辐射安全性等) security evaluation (such as biocompatibility, bio-security, electric security, radiation security, etc.)
	7. 软件核心功能



	core function of the software
	8.产品符合的国家/行业标准 national/industrial standards
	9.适用范围： applicable scope (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
	10.使用方法 usage
	11.禁忌症 contraindication
	12.防范措施和警告 precautionary measure and warning
	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