欧盟医疗器械MDR法规临床评价相关要求

产品名称	欧盟医疗器械MDR法规临床评价相关要求
公司名称	国瑞中安集团-实验室
价格	.00/件
规格参数	
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产品详情

临床评价相关要求新法规提出：1.要求根据Article61和附录XIV partA执行、评估、报告和更新临床评价资料；2.提出对特定III类和IIb类器械，CER中要考虑咨询专家小组的意见；3.对植入和III类器械，提出考虑临床研究；4.要求CER按照PMCF取得数据进行更新；5.针对III类和可植入器械，提出了CER更新的频率；6.明确证明实质等同性需考虑的特点；7.要求其与风险管理的相互作用

Relevant requirements for clinical evaluation

The new regulations propose:

1. It is required to implement, evaluate, report and update clinical evaluation data according to Article 61 and Appendix XIV partA;

2. Propose that the opinions of the consulting expert group should be considered in CER for specific Class III and IIb devices;

3. For implants and Class III devices, clinical research should be considered;

4. Require the CER to update the data obtained according to PMCF;

5. For Class III and implantable devices, the frequency of CER update is proposed;

6. Specify the characteristics to be considered for proving substantive equivalence;

7. Requirements for interaction with risk management