
CHAPTER 9

Federal Regulation of Medical Devices Clinical Trial Design/Outcome Studies;

9.1 Federal Regulation of Medical Devices

- 9.1.1 The Law (including amendments)
- 9.1.2 Organization of FDA
- 9.1.3 Classification of Devices
- 9.1.4 Process of Assessment
 - 10.1.4.1 510(k) Substantial Equivalence
 - 10.1.4.2 Premarket Approval
- 9.1.5 Clinical Trials (Investigational Device Exemption)
- 9.1.6 Labeling
- 9.1.7 Tripartite Biocompatibility Guidance
- 9.1.8 Standards
- 9.1.9 Good Manufacturing Procedures
- 9.1.10 Good Laboratory Practices

9.2 Clinical Trial Design