CHAPTER 11

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

10.1 Federal Regulation of Medical Devices

- 10.1.1 The Law (including amendments)
- 10.1.2 Organization of FDA
- 10.1.3 Classification of Devices
- 10.1.4 Process of Assessment
  - 10.1.4.1 510(k) Substantial Equivalence
  - 10.1.4.2 Premarket Approval
- 10.1.5 Clinical Trials (Investigational Device Exemption)
- 10.1.6 Labeling
- 10.1.7 Tripartite Biocompatibility Guidance
- 10.1.8 Standards
- 10.1.9 Good Manufacturing Procedures
- 10.1.10 Good Laboratory Practices

10.2 Clinical Trial Design