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