FDA REPORT

Outline

Description of the Device

Indication

Intended Use

FDA Classification

Preclinical Tests
  Laboratory functional tests
  Performance tests
  Mechanical tests (if relevant)
  Biological (Safety) Tests (FDA Tripartite Guidance)
  Efficacy testing in animals (animal models related to the human use of the device)

Clinical Tests
  Patient population
  Controls
  Sample size (statistical power calculation)
  Outcome variables to be measured
  Informed Consent Form