

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