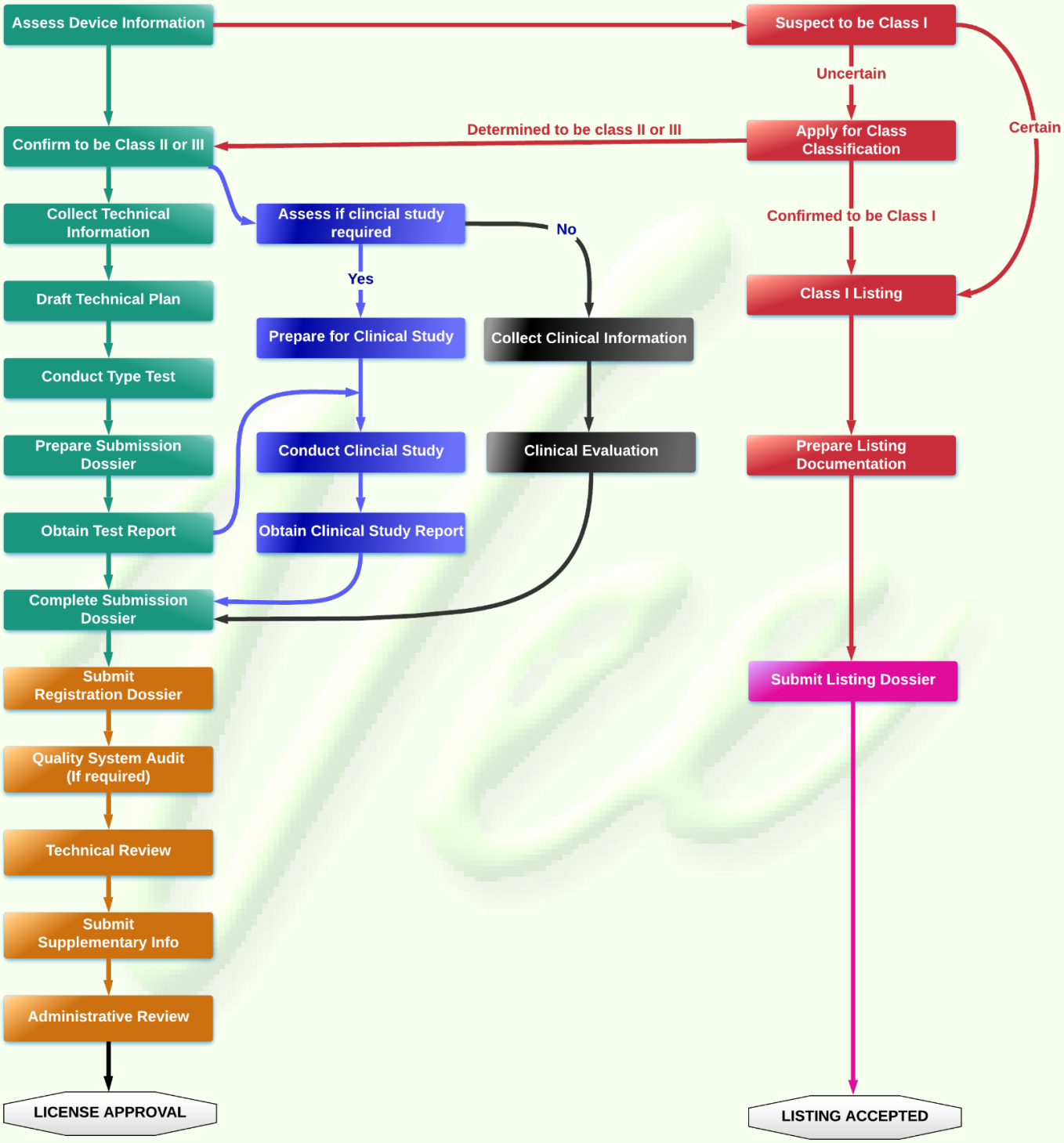
## REGISTRATION PROCESS



# MARKET ACCESS TO CHINA

## DOCUMENTS REQUIRED

### Administrative Information
- Model List
- Quality System Certificate
- Authorization Letter
- Declaration of Conformity

### Device Information
- Product Descriptions
- Intended uses/indications
- Contraindications/Warnings
- Device History
- Overseas Marketing Approvals

### Non-clinical Test Data
- Risk Management File
- Essential Requirement Checklist
- Complied Standards
- Bench Test Reports
- Shelf-life & Packaging Test Data

### Clinical Data
- Clinical Overview
- Clinical Study Report
- Clinical Evaluation Report
- Other Clinical Data

### Label Information
- Packing Material Artworks
- Pack Insert or Product Manual
- Information for Doctor
- Information for Patient
- Technical Specifications