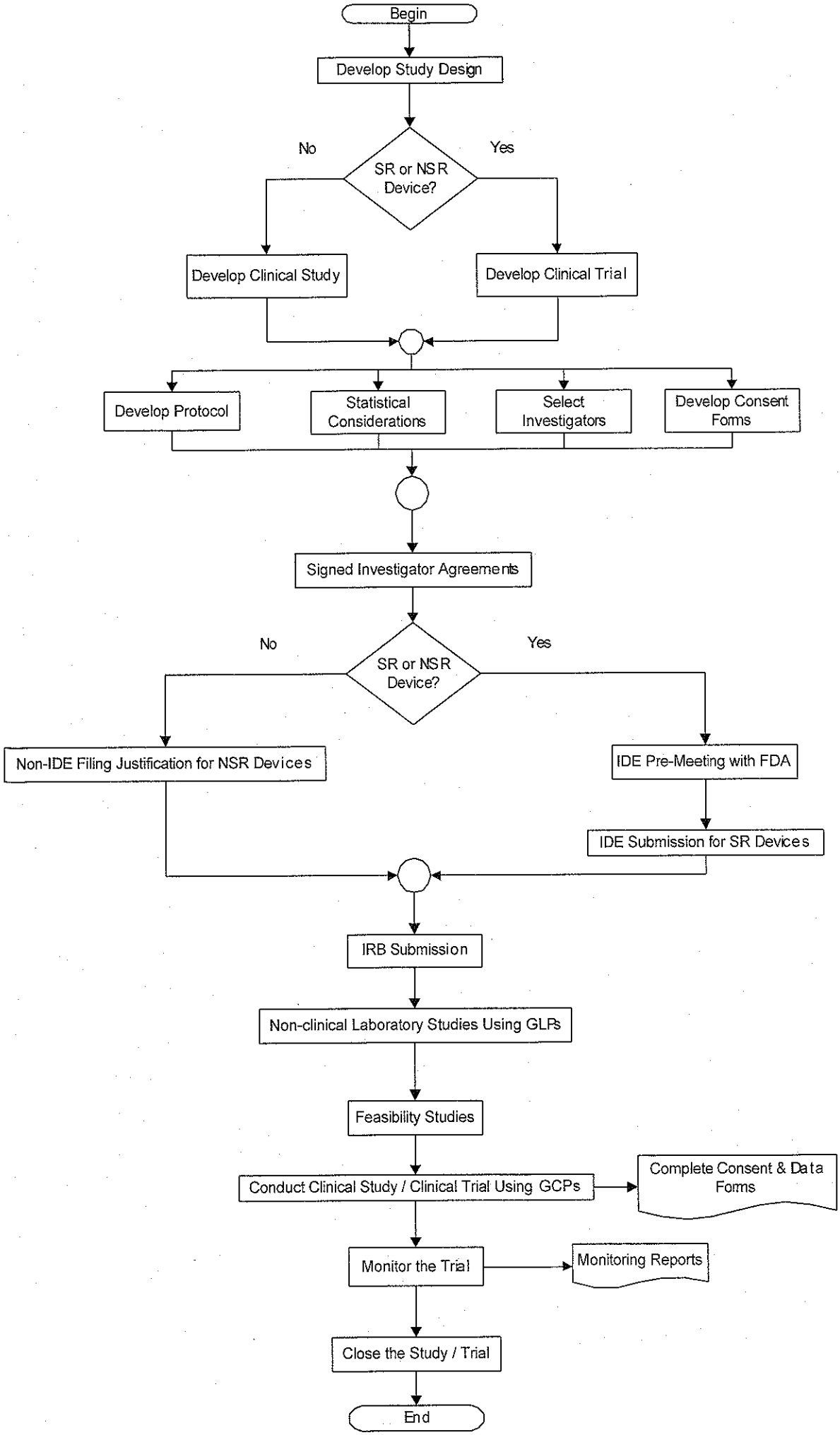
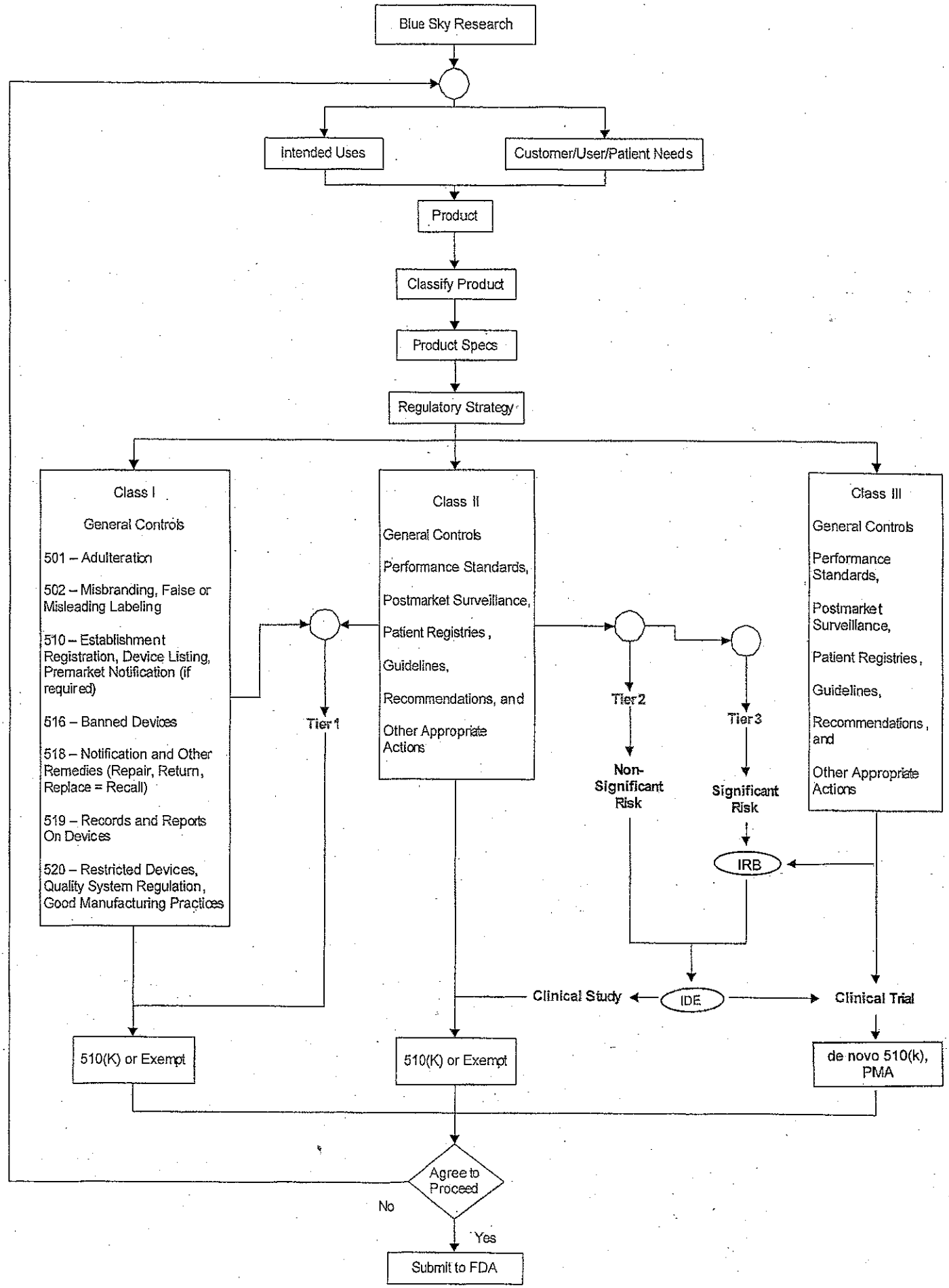

Begin
Develop Study Design
No
SR or NSR Device?
Yes
Develop Clinical Study
Develop Clinical Trial
Develop Protocol
Statistical Considerations
Select Investigators
Develop Consent Forms
Signed Investigator Agreements
No
SR or NSR Device?
Yes
Non-IDE Filing Justification for NSR Devices
IDE Pre-Meeting with FDA
IDE Submission for SR Devices
IRB Submission
Non-clinical Laboratory Studies Using GLPs
Feasibility Studies
Conduct Clinical Study / Clinical Trial Using GCPs
Complete Consent & Data Forms
Monitor the Trial
Monitoring Reports
Close the Study / Trial
End


Blue Sky Research
Intended Uses
Customer/User/Patient Needs
Product
Classify Product
Product Specs
Regulatory Strategy
Class I
General Controls
501 – Adulteration
502 – Misbranding, False or Misleading Labeling
510 – Establishment Registration, Device Listing, Premarket Notification (if required)
516 – Banned Devices
518 – Notification and Other Remedies (Repair, Return, Replace = Recall)
519 – Records and Reports On Devices
520 – Restricted Devices, Quality System Regulation, Good Manufacturing Practices
Class II
General Controls
Performance Standards,
Postmarket Surveillance,
Patient Registries,
Guidelines,
Recommendations, and
Other Appropriate Actions
Class III
General Controls
Performance Standards,
Postmarket Surveillance,
Patient Registries,
Guidelines,
Recommendations, and
Other Appropriate Actions
Tier 1
Tier 2
Tier 3
Non-Significant Risk
Significant Risk
IRB
IDE
Clinical Study
Clinical Trial
510(K) or Exempt
510(K) or Exempt
de novo 510(k), PMA
Agree to Proceed
No
Yes
Submit to FDA