Appendix 1: REGULATORY DECISION TREE (21 CFR PART 812) for IVD INVESTIGATIONAL STUDIES

Is it a Pre-amendments device (other than transitional) used according to the labeling in effect at the time, or is it a device, determined by FDA as substantially equivalent (SE) to a pre-amendments device, used according to the labeling reviewed as part of the SE determination?

Yes

Study is exempt from 21 CFR Part 812, except for 812.119

No

Is it an invasive device? → Significant risk? → Apply to FDA for IDE

Yes

No

Follow 812.2(b) – abbreviated IDE requirements

Yes

No

Follow 812.2(b) – abbreviated IDE requirements

Does the study involve invasive sampling? → Significant risk? → Apply to FDA for IDE

Yes

No

Will it be used as a diagnostic procedure without confirmation by a medically established product or procedure?

Yes

No

Significant risk? → Apply to FDA for IDE

Yes

No

Follow 812.2(b) – abbreviated IDE requirements

If the sponsor complies with the applicable requirements of 21 CFR 809.10(c), the study is exempt from 21 CFR Part 812, with the exception of 812.119.