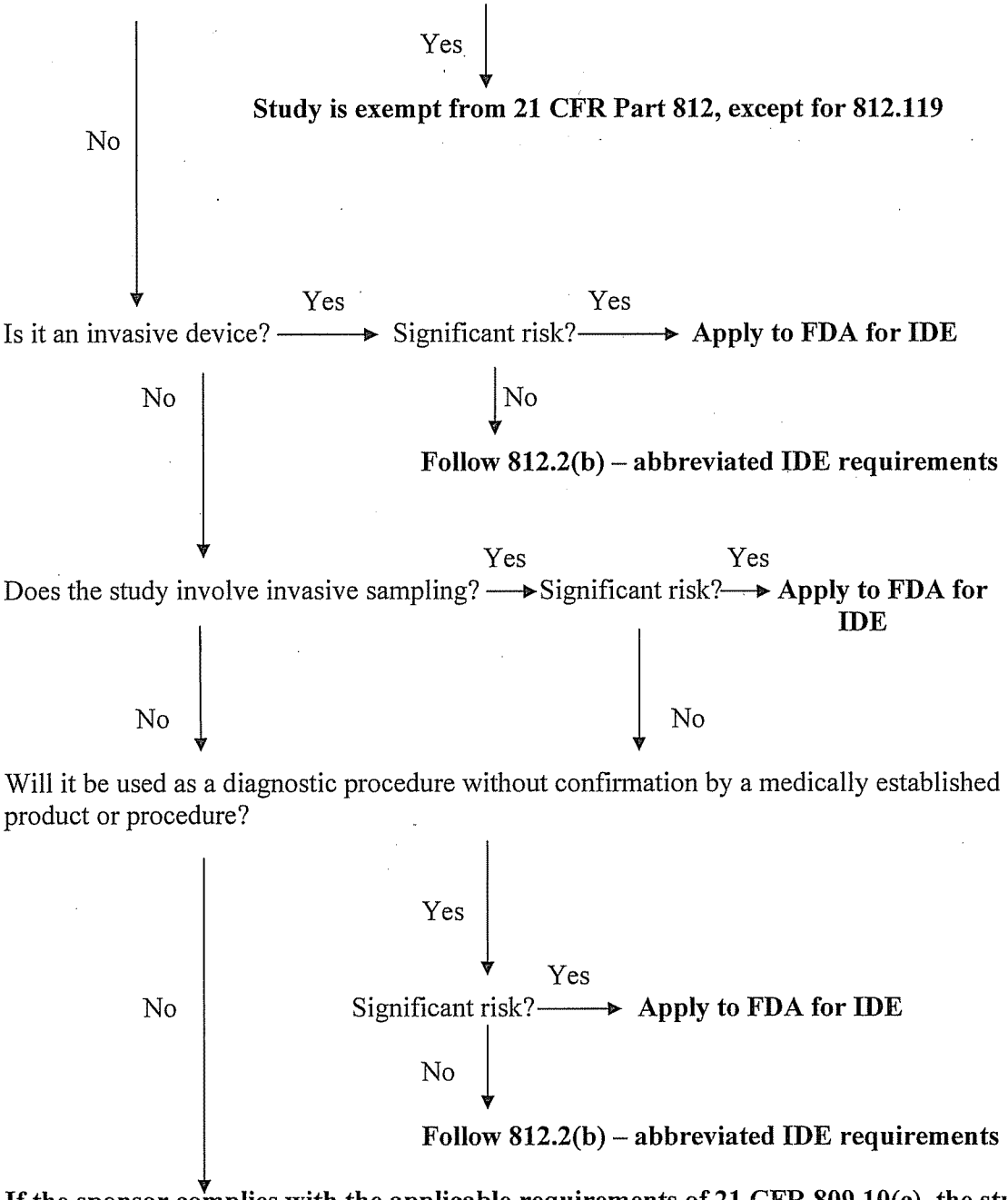
Appendix 1: REGULATORY DECISION TREE (21 CFR PART 812) for IVD INVESTIGATIONAL STUDIES

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?



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.