

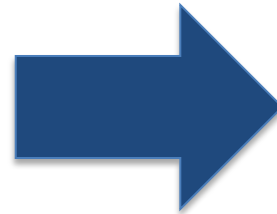
Exempt study



First, identify if the use of the device for this study is exempt from the requirement for an IDE at 21 CFR 812.2(c)1-7

No IDE

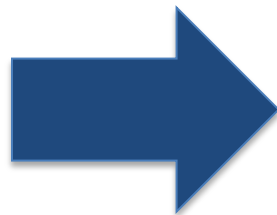
Significant Risk(SR) Study



If the device study is not exempt, then evaluate the risk of the device in the study. Determine if the device study meets the criteria of a significant risk device study at 21 CFR 812.3.

Submit IDE to FDA

Non-Significant Risk (NSR) Study



If the device study does not meet the criteria for a SR device, then it is a non-significant risk (NSR) study. Obtain IRB approval and meet the abbreviated requirements at 21 CFR 812.2(b).

No IDE with the FDA (Abbreviated IDE)