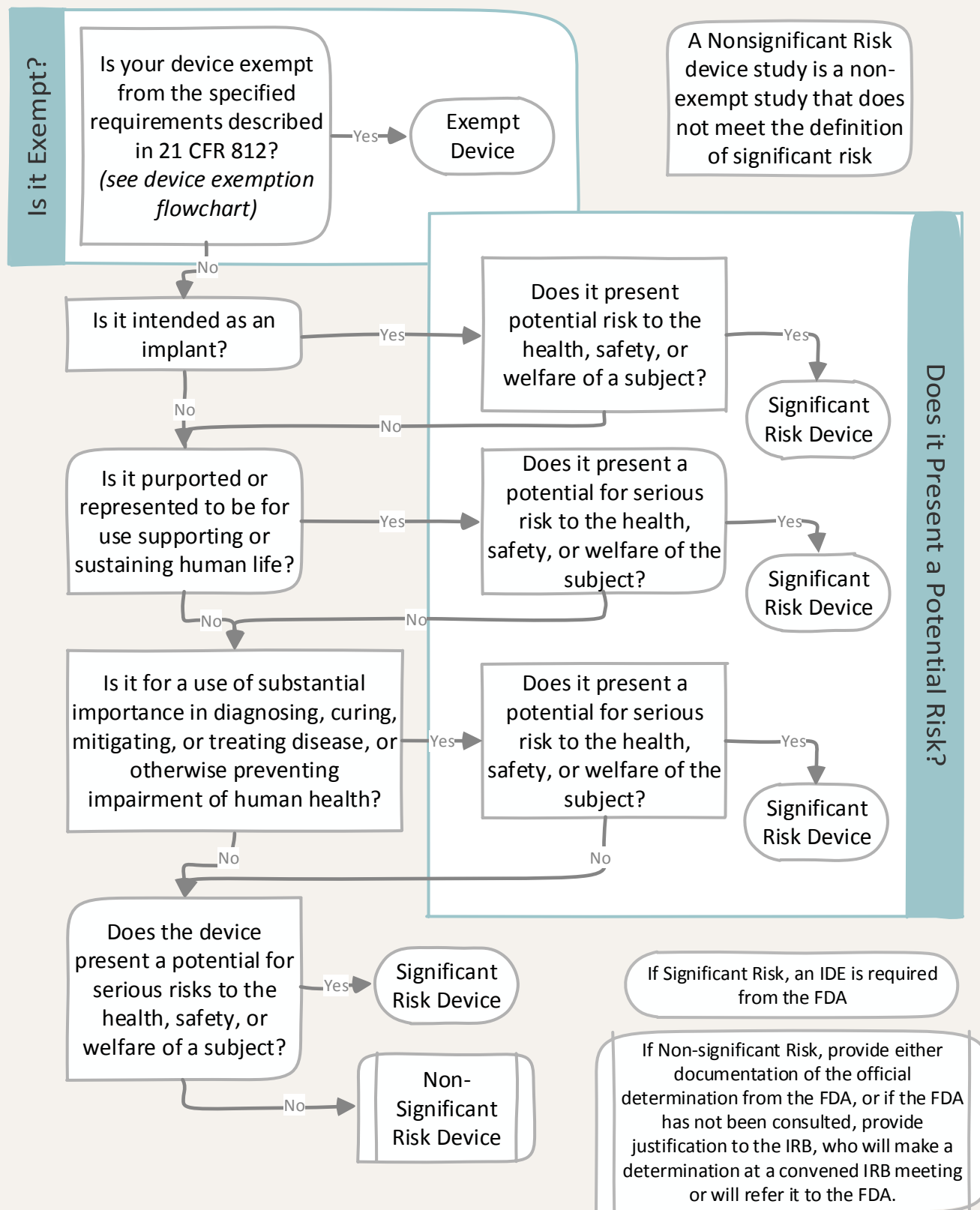


Is the Medical Device Study Classified as a Significant Risk or Nonsignificant Risk Device?



What Should IRBs Consider When Making the SR and NSR Determination?

- What is the basis for the risk determination? The risk determination is based on the proposed use of a device in an investigation, and not on the device alone.
- What is the nature of harm that may result from use of the device? SR studies are those that present a potential for serious risk to the health, safety, or welfare of a subject.
- Will the subject need to undergo an additional procedure as part of the investigational study, for example, a surgical procedure? IRBs should consider the potential harm the procedure could cause as well as the potential harm caused by the device.

NOTE: IRBs make the SR/NSR determination before the IRB conducts its review of the study under Part 56. The judgment about whether a study poses a significant risk or nonsignificant risk is based on the significance of the potential harm that may result from participation in the study, including the use of the device; whereas the IRB's decision to approve a study for implementation is based on the study's risk-benefit assessment.

	Nonsignificant Risk Device	<i>Vs.</i>	Significant Risk Device
Determination/ Approval Process	Determination by the IRB at a convened meeting. No FDA submission required.		IDE Application Submission and Approval by the FDA.
Requirements	Abbreviated Requirements related to labeling, IRB approval, informed consent, monitoring, records storage & retention, reporting to the FDA, and prohibition against promotion.		All requirements of nonsignificant risk device studies plus additional requirements (see FDA website for more information).