Guidance for Investigational Device Studies

Device studies are categorized into three types according to the Investigational Device Exemption regulations at 21 CFR 812:

- exempt studies – these studies are exempt from the requirements of 21 CFR Part 812. Examples of exempt studies include: consumer preference testing, testing of a device modification, and diagnostic device studies (e.g., in vitro diagnostic studies). Visit the links below for additional information.
- significant risk (SR) device studies – these studies require an approved IDE (Investigational Device Exemption) from the FDA and must comply with the regulations at 21 CFR 812. Please refer to the FDA Information Sheet Guidance "Significant Risk and Nonsignificant Risk Medical Device Studies" (linked below) for specific examples of SR device studies.
- nonsignificant risk (NSR) device studies – these studies must meet the abbreviated IDE requirements at 21 CFR 812.2(b). Please refer to the FDA Information Sheet Guidance "Significant Risk and Nonsignificant Risk Medical Device Studies" (linked below) for specific examples of NSR device studies.

You may need to acquire additional information and/or documentation from the study sponsor or the FDA to submit to the IRB, depending on what type of device study you have. The decision trees that follow will help you determine whether you have a device study, whether FDA regulations apply to your study, and what category your study falls into.

If you have questions about this document or specific questions about your study, please contact Misty White, IRB Coordinator, at 303.735.3702 or misty.white@colorado.edu.

FDA Information Sheet Guidance:

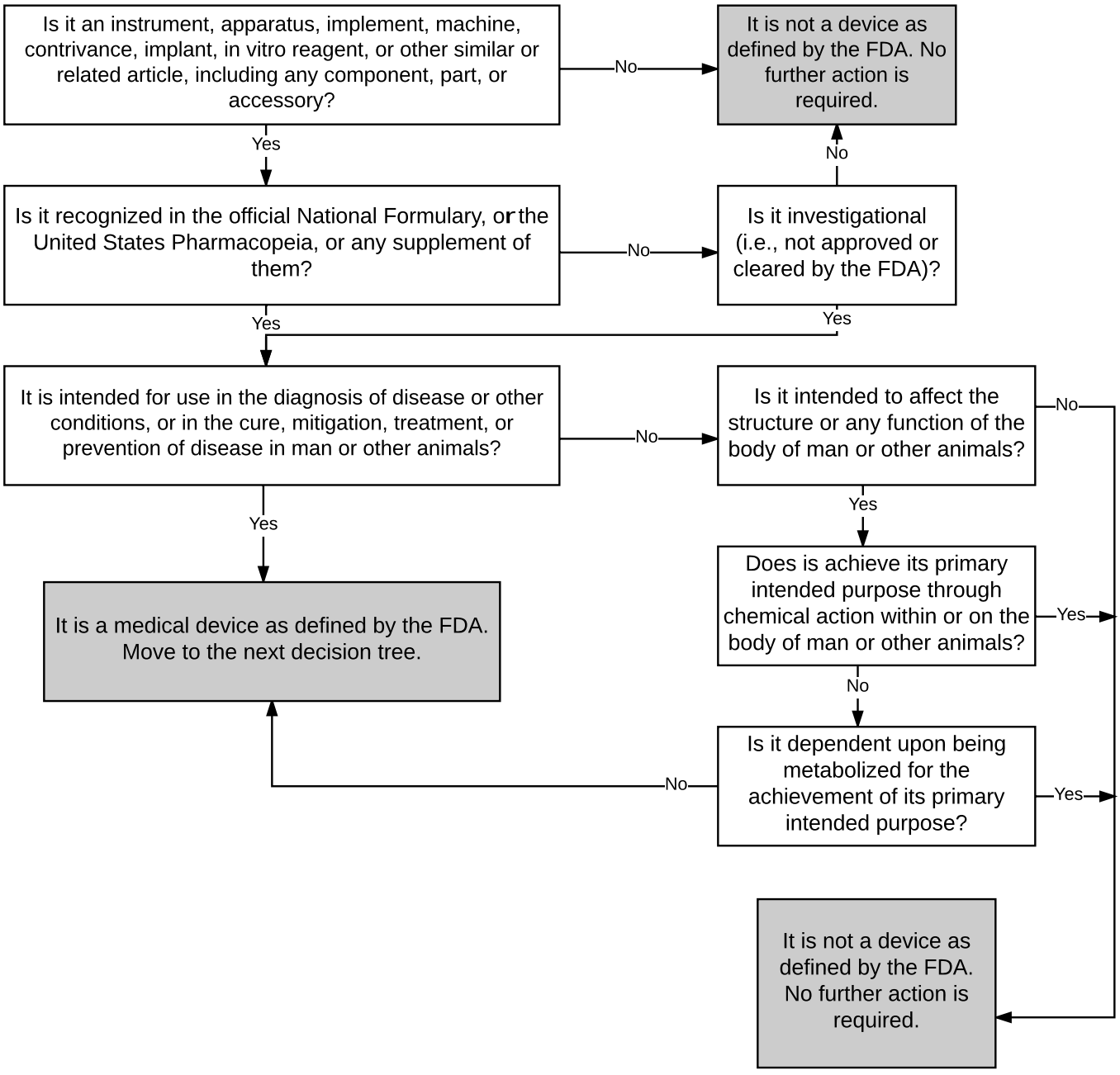
Frequently Asked Questions About Medical Devices

Significant Risk and Nonsignificant Risk Medical Device Studies

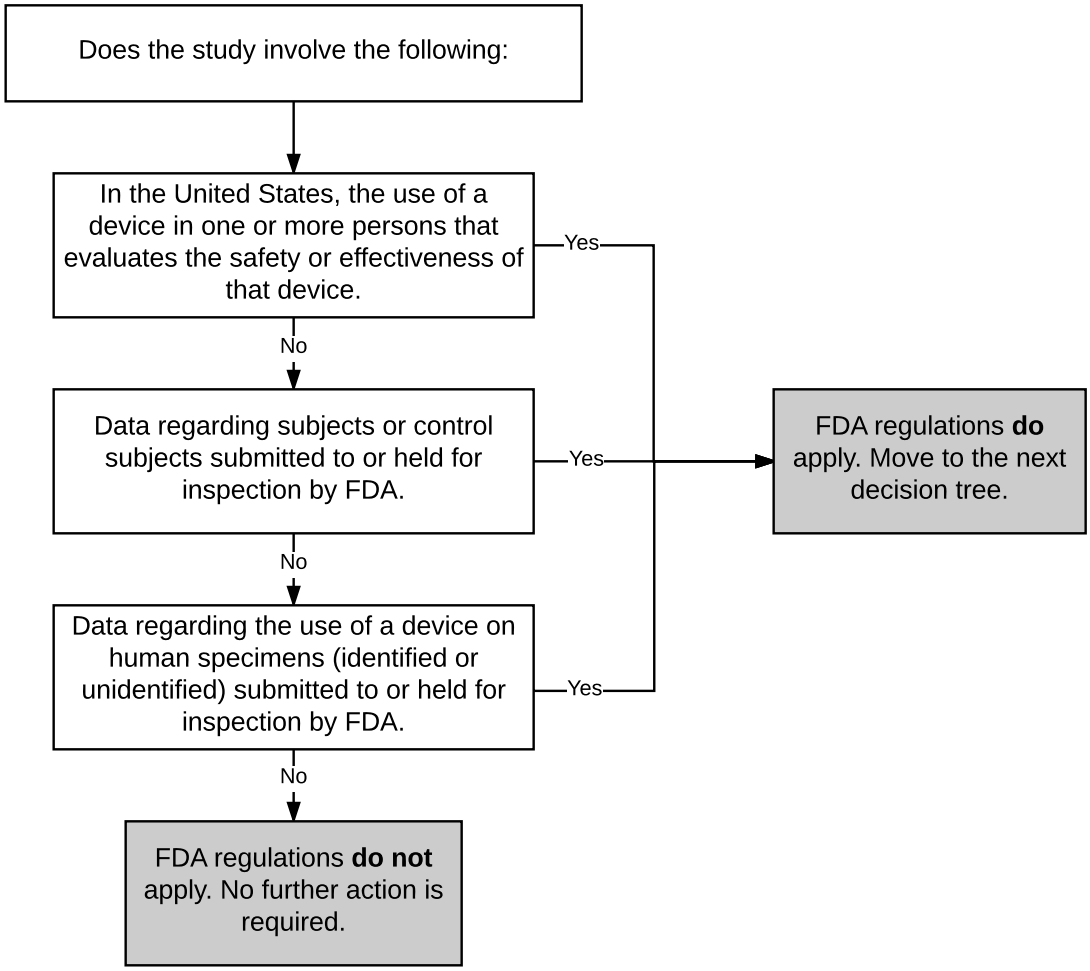
Link to FDA regulations:

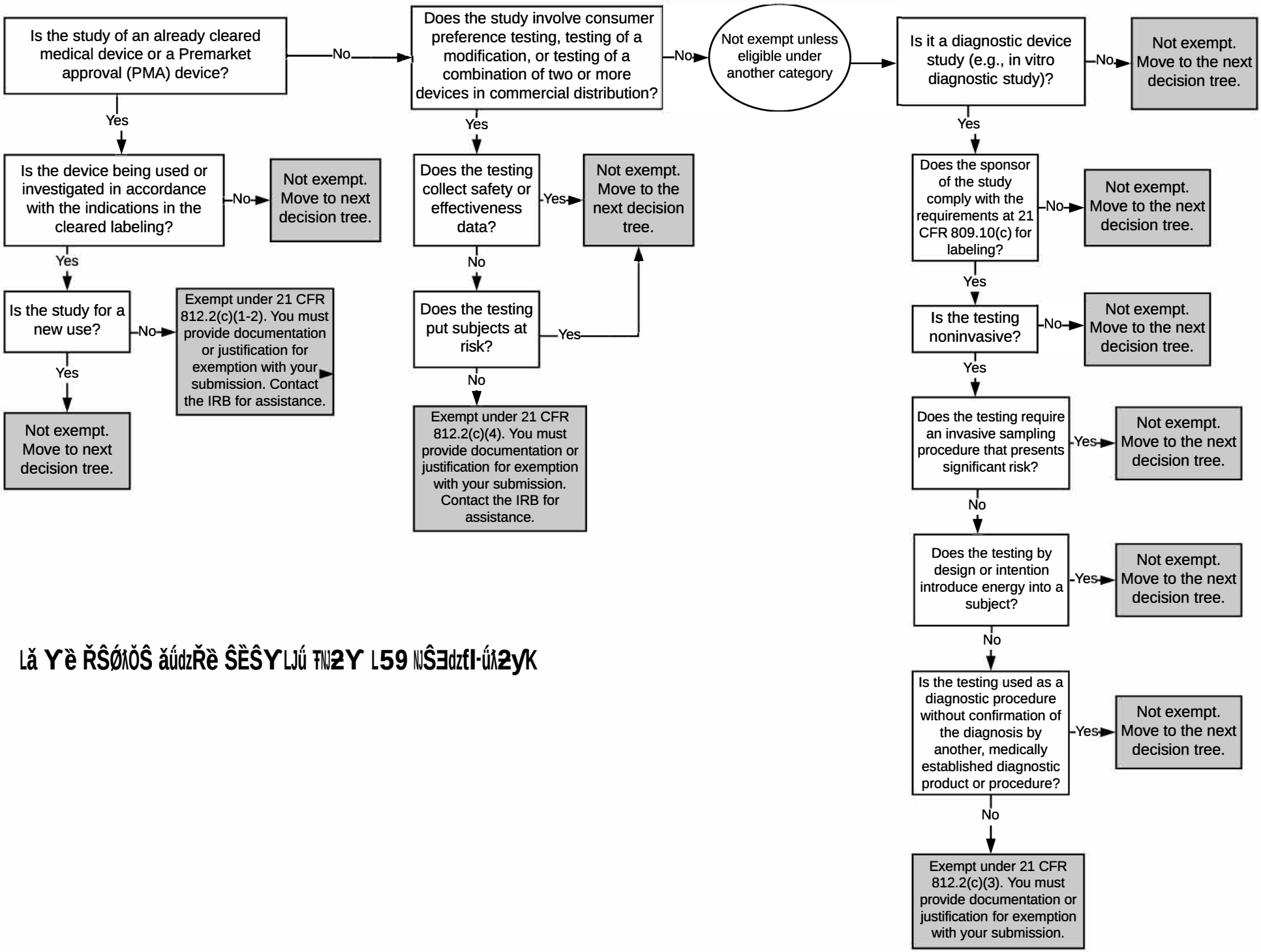
21 CFR Part 812

Do I have a medical device?



Do FDA regulations apply to my device study?





Lă Yè ŘŜØλŎŜ ăűdzŘè ŜĚŜYLJű ŦN2Y L59 NŜƎdzfl-ûλ2yK

Is my device study classified as SR or NSR?