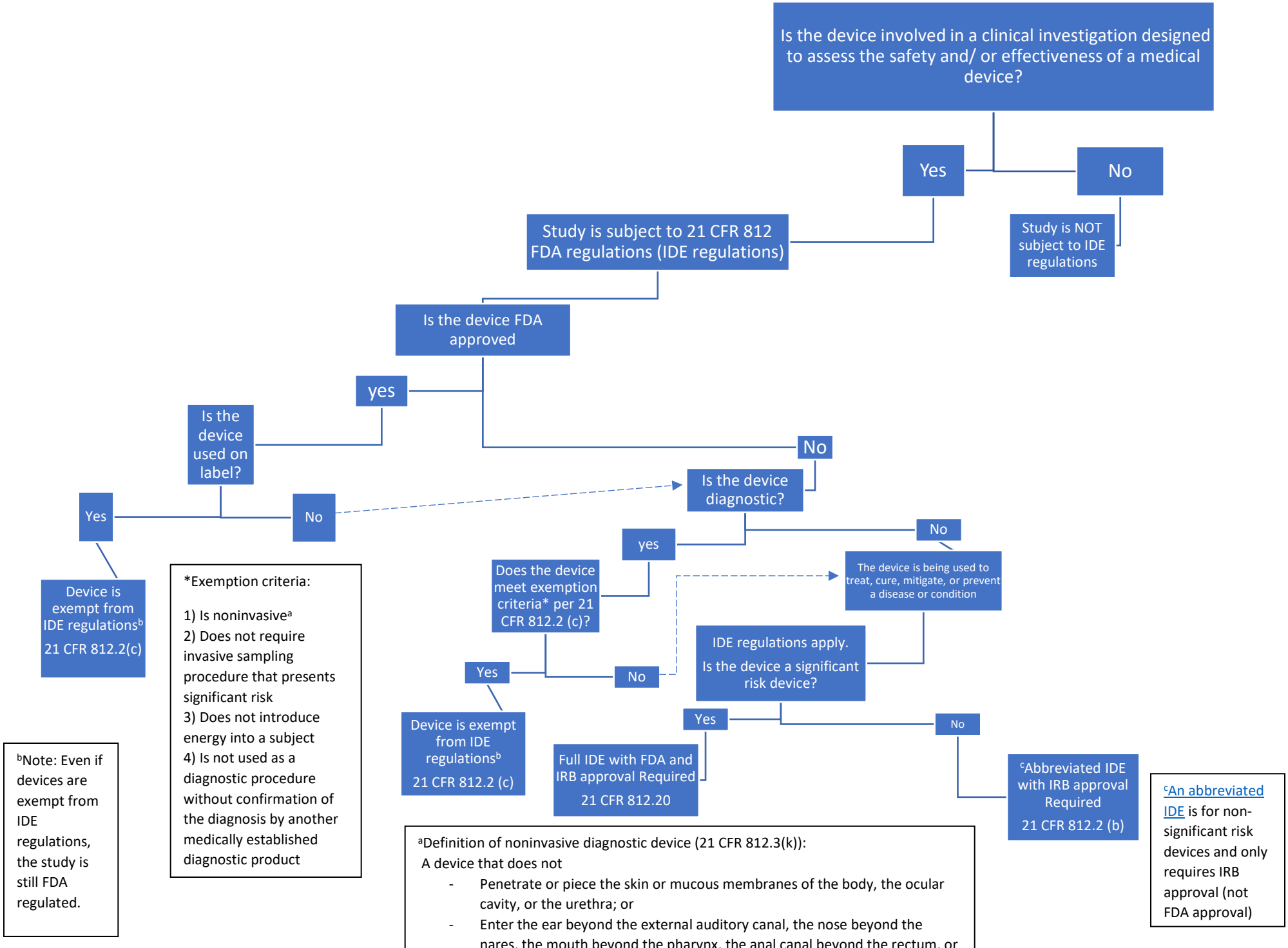
Is the device involved in a clinical investigation designed to assess the safety and/ or effectiveness of a medical device?
Yes
No
Study is NOT subject to IDE regulations
Study is subject to 21 CFR 812 FDA regulations (IDE regulations)
Is the device FDA approved
yes
No
Is the device used on label?
Yes
No
Is the device diagnostic?
yes
No
Does the device meet exemption criteria* per 21 CFR 812.2 (c)?
The device is being used to treat, cure, mitigate, or prevent a disease or condition
Yes
No
IDE regulations apply.
Is the device a significant risk device?
Yes
No
Device is exempt from IDE regulations[b]
21 CFR 812.2(c)
Device is exempt from IDE regulations[b]
21 CFR 812.2 (c)
Full IDE with FDA and IRB approval Required
21 CFR 812.20
[c]Abbreviated IDE with IRB approval Required
21 CFR 812.2 (b)
*Exemption criteria:
1) Is noninvasive[a]
2) Does not require invasive sampling procedure that presents significant risk
3) Does not introduce energy into a subject
4) Is not used as a diagnostic procedure without confirmation of the diagnosis by another medically established diagnostic product
[b]Note: Even if devices are exempt from IDE regulations, the study is still FDA regulated.
[a]Definition of noninvasive diagnostic device (21 CFR 812.3(k)):
A device that does not
- Penetrate or piece the skin or mucous membranes of the body, the ocular cavity, or the urethra; or
- Enter the ear beyond the external auditory canal, the nose beyond the nares, the mouth beyond the pharynx, the anal canal beyond the rectum, or the vagina beyond the cervical os
[c]An abbreviated IDE is for non-significant risk devices and only requires IRB approval (not FDA approval)

What is an Investigational Device Exemption (IDE)?

- An FDA-approved investigational device exemption (IDE) permits a device that otherwise would be required to comply with a performance standard or to have pre-market approval to be shipped lawfully for the purpose of conducting investigations of that device. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated. (21 CFR 812.1)

Definitions:

- **Medical Device** – An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
  1. Recognized in the official National Formulary, or the United States Pharmacopeoia, or any supplement to them,
  2. Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
  3. Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and

  which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o). Per section 201(h) of the Food, Drug, and Cosmetic Act.

- **Investigational Device** - a device, including a transitional device, that is the object of an investigation.
- **Investigation** - means a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device
- ***Category A Device (experimental)** - a device where absolute risk of device is unknown, meaning the efficacy and safety issues have not been determined in the following conditions 1) the device is new, FDA is unsure whether the device is safe and effective for proposed intended or indications for use. No equivalent device has answered the questions of efficacy and safety and no De Novo request has been granted; 2) the indication or intended use of the proposed device is new for the proposed device or a similar device; or 3) the new technical characteristics compared to the legally marketed device does have changed, rendering available clinical and non-clinical data insufficient. CMS approval of a Category A (Experimental) IDE study will allow coverage of routine care items and services provided for the study, but not for the Category A device itself.
- ***Category B Device (non-experimental/ investigational)** - a device where incremental risk is the element in question, meaning the efficacy and safety have been resolved for that device type from previous trials resulting in premarket approval or clearance for this type of device. The following conditions 1) no current PMA, 510(k), De Novo approval has been issued for proposed or similar device, however feasibility data from proposed or similar device has addressed initial questions of efficacy and safety for the FDA for proposed intended or indications for use; 2) this is a new indication or intended use of the proposed device, however satisfactory information exists as it is similar to previous indication or intended use for the proposed device or a similar device; 3) the new technical characteristics are similar when compared to a legally marketed device, rendering available clinical and non-clinical data sufficient.

***When using the IDE decision tree to determine whether an IDE is required for your device and study, be mindful of the CMS submission process once approvals are secured.**