Flowchart

Is this study subject to FDA regulations under 21 CFR 812? Devices

This flow chart was prepared by Molly Klote, MD Lieutenant Colonel, Medical Corps, US Army

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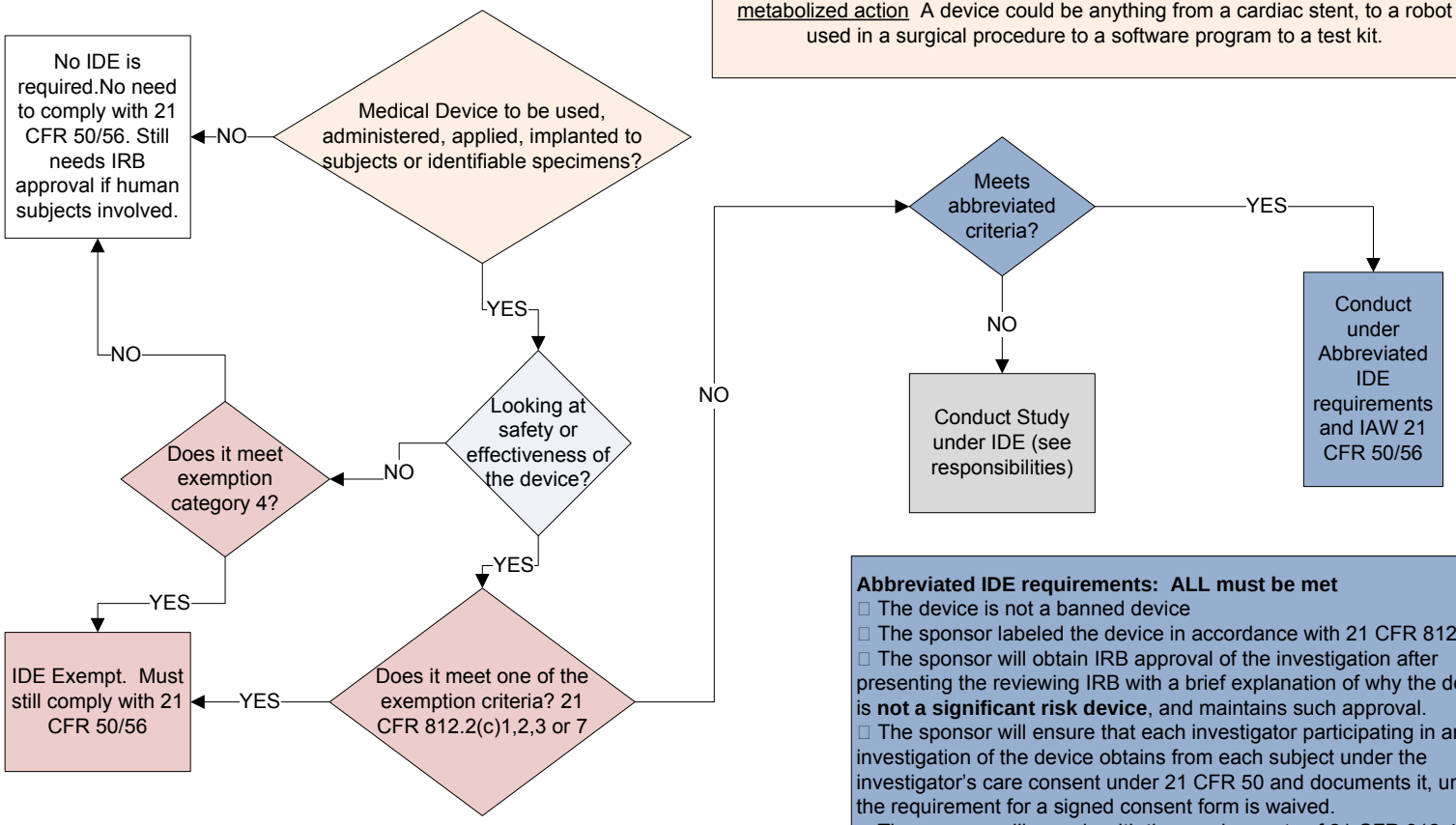
Understanding the Guidelines for FDA Regulations for Drug and Device Determinations: A Visual Learner's Approach.

Is this study subject to FDA regulations at 21 CFR 812? DEVICES

Medical Device Definition:An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent . . .or component, part, or accessory. . . intended to diagnose a disease or condition or to cure, mitigate, treat, or for prevention of disease or it affects the structure or function of the body…..and does not achieve its primary purpose through chemical action ...or by being metabolized action A device could be anything from a cardiac stent, to a robot used in a surgical procedure to a software program to a test kit.



Abbreviated IDE requirements: ALL must be met

- The device is not a banned device
- The sponsor labeled the device in accordance with 21 CFR 812.5.
- The sponsor will obtain IRB approval of the investigation after presenting the reviewing IRB with a brief explanation of why the device is **not a significant risk device**, and maintains such approval.
- The sponsor will ensure that each investigator participating in an investigation of the device obtains from each subject under the investigator's care consent under 21 CFR 50 and documents it, unless the requirement for a signed consent form is waived.
- The sponsor will comply with the requirements of 21 CFR 812.46 with respect to monitoring investigations;
- The sponsor will maintain the records required under 21 CFR 812.140(b)(4) and (5) and make the reports required under 21 CFR 812.150(b) (1) through (3) and (5) through (10);
- The sponsor will ensure that participating investigators will maintain the records required by 21 CFR 812.140(a)(3)(i) and make the reports required under 812.150(a) (1), (2), (5), and (7); and
- The sponsor will comply with the prohibitions in 21 CFR 812.7 against promotion and other practices

Exemption categories 21 CFR 812.2(c):

1. Device other than transitional device, in commercial distribution before May 28,1976, when used or investigated IAW the indications in labeling in effect at that time.
2. Device, other than transitional device, introduced after May 28,1976, that the FDA has determined to be substantially equivalent to a device in commercial distribution before May 28, 1976, that is being used IAW the indications in the labeling FDA reviewed.
3. See below
4. A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the purpose of the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.
5.-6. animal devices
7. A custom device ((21 CFR 812.3(b)), unless the device is being used to determine safety or effectiveness for commercial distribution.

A device is legally marketed in the US if FDA has approved a Pre-Market Application (PMA), if FDA has granted marketing clearance (510k), or if the device is exempt from PMA/510k requirements.

The status of all devices should be checked against the FDA/ scripts/cdrh/cfdocs website.

Exemption 21 CFR 812.2(c)(3)
Diagnostic Device testing exemption criteria: ALL criteria must be met

1. Is **noninvasive (see def'n)**
2. Does not require an invasive sampling procedure that presents significant risk
3. does not by design or intention introduce energy into a subject
4. Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established product or procedure.

Significant Risk (SR) and Nonsignificant Risk(NSR) Study Determinations: Study sponsors are responsible for making the initial risk determination for the study and presenting it to the IRB. Unless FDA has already made a risk determination for the study, the IRB must review the Sponsor's SR or NSR determination and modify the determination if the IRB disagrees with the sponsor. The IRB should use the criteria in the "Information sheet Guidance for IRBs, Clinical Investigators, and Sponsors: Significant Risk and Nonsignifcant risk Medical Device Studies" when reviewing a study and making SR/NSR decision.

Noninvasive device or procedure definition: DOES NOT

1. penetrate the skin or mucous membranes of the body, the ocular cavity or urethra, or
2. 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. Simple venipuncture is considered non invasive. The use of surplus body samples of body fluids or tissues that are left over from samples taken for non-investigational purposes is also considered non invasive.

Institutional responsibilities

1. IRB must review under 32 CFR 219 and 21 CFR 50/56, 21 CFR 812 and AR 40-7.
2. IRB must review the device manual
3. IRB must assign study risk determination

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