Significant Risk vs Non-Significant Risk Device Determination

Question 1: Does your device do any of the following?

1. Intended as an implant and presents a potential for serious risk to the health, safety or welfare of a person
2. Represented or intended to be for the use supporting or sustaining human life and presents a potential for serious risk to the health, safety or welfare of a person
3. Is for a use of substantial importance in diagnosing, curing, mitigating, or treating a disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety or welfare of a person
4. Otherwise presents a potential for serious risk to the health, safety or welfare of a person

Yes to question 1: Your device is a significant risk device and requires an IDE to be filed with the FDA to use it in clinical trials. Clinical trials must follow all applicable device regulations under 21 CFR 812.

No to question 1: Your device is considered a non-significant risk device and you will be required to make a non-significant risk determination to the IRB for the use of this device for your clinical trial. The IRB must concur with your non-significant risk determination or they can request you to submit your device to the FDA for a determination.

Question 2 (after no to question 1): Does any of the following apply to your device and its intended use in your clinical trial?

1. A legally marketed device when used in accordance with its labeling
2. A diagnostic device if it complies with the labeling requirements in 21 CFR 809.10(c) and if testing:
    a. Is noninvasive,
    b. Doesn't require an invasive sampling procedure that presents significant risk,
    c. Doesn't by design or intention to introduce energy into a person,
    d. AND isn't used as a diagnostic procedure without confirmation by another medically established diagnostic product or procedure
3. Consumer preference testing, testing of a modification, or testing of a combination of devices if the device(s) are legally marketed device(s) where the device(s) have an approved PMA, cleared 510(k) or are 510(k) exempt AND if the testing is not for the purpose of determining safety or effectiveness and doesn't put someone at risk
4. A device intended solely for veterinary use
5. A device shipped solely for research with laboratory animals and contains the labeling "CAUTION- Device for investigational use in laboratory animals or other tests that do not involve human subjects"

Yes to question 1: Your device is IDE exempt and IDE exemption is described in 21 CFR 812.2(c)

No to question 2: Your device is a non-significant risk device and is subject to abbreviated IDE requirements under 21 CFR 812.2(b) during your clinical trial. You are required to provide an explanation to the IRB of record that the device is a non-significant risk device for their concurrence of the device's risk determination. If the FDA disagrees with your non-significant risk determination, you will be required to submit to the FDA for a device risk determination.

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