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

This document is intended to be guidance only and cannot replace a formal determination from the FDA.

Is it intended as an implant?

Yes  
A Nonsignificant Risk device study is a non-exempt study that does not meet the definition of significant risk

No

Is it purported or represented to be for use supporting or sustaining human life?

Yes  
Does it present potential risk to the health, safety, or welfare of a subject?

Yes  
Significant Risk Device

No  
Does it present potential for serious risk to the health, safety, or welfare of the subject?

Yes  
Significant Risk Device

No  
Does the device present a potential for serious risks to the health, safety, or welfare of a subject?

Yes  
Significant Risk Device

No  
Non-Significant Risk Device

Is it for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health?

Yes  
Does it present potential for serious risk to the health, safety, or welfare of the subject?

Yes  
Significant Risk Device

No  
Yes  
Does it present potential risk to the health, safety, or welfare of a subject?

Yes  
Significant Risk Device

No  
Exempt Device

Does it present potential risk to the health, safety, or welfare of a subject?

Yes  
Significant Risk Device

No  
Does it present potential for serious risk to the health, safety, or welfare of the subject?

Yes  
Significant Risk Device

No  
Non-Significant Risk Device

If Significant Risk, an IDE is required from the FDA.

If Non-significant Risk, provide either documentation of the official determination from the FDA, or if the FDA has not been consulted, provide justification to the IRB, who will make a determination at a convened IRB meeting or will refer it to the FDA.

For More Information, Please Contact:
Human Research Protection Program
Institutional Review Board
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