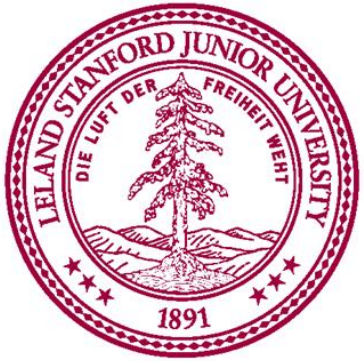
Medical Devices

Research Compliance Office
Stanford University



What is a 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….

- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or
- intended to affect the structure or any function of the body, and which does not achieve its primary intended purposes through chemical action within or on the body ….

(FD&C Act; 21 USC 321(h))

Medical Device Studies

Research that assesses the safety or effectiveness of a medical device must fall into one of the following categories:

- IDE Exempt
- Non-Significant Risk Device (NSR)
- Significant Risk Device

IDE Exempt Device Studies

- Marketed medical devices being used according to their approved labeling/indications
- Studies not evaluating safety or effectiveness
- In Vitro Diagnostic (IVD) devices

Non-Significant Risk Device Studies

- Is NOT intended as an implant and does NOT present a potential for serious risk to the health, safety, or welfare of a subject;
- Is NOT purported or represented to be for use supporting or sustaining human life and does NOT present a potential for serious risk to the health, safety, or welfare of a subject;
- Is NOT for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and does NOT present a potential for serious risk to the health, safety, or welfare of a subject; or
- Otherwise does NOT present a potential for serious risk to the health, safety, or welfare of a subject.

Non-Significant Risk Device Studies

- Sponsors are responsible for making the initial risk determination

- IRB reviews the sponsor's NSR rationale and makes the final determination.

Significant Risk Device Studies

- presents a potential for serious risk to the health, safety, or welfare of a subject;

- requires an IDE from the FDA

Questions?


Research Compliance Office
RCO
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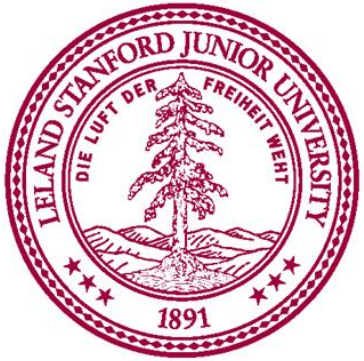
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