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| The purpose of this checklist is to provide support for IRB members following the WORKSHEET: Criteria for Approval (HRP-314) when research involves an abbreviated IDE. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB)   * For initial review and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the IRB member completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The IRB member uploads this checklist in the protocol file. | |
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| 1. NON-SIGNIFICANT RISK DEVICE STUDY (Check if “Yes”. If all are checked, the device is a non-significant risk device.) | |
|  | • The device is **NOT** intended as an implant, **OR**  • The device is an implant but there is **NO** potential for serious risk to the health, safety, or welfare of a subject. |
|  | • The device is **NOT** purported or represented to be for a use in supporting or sustaining human life, **OR**  • The device is purported or represented to be for a use in supporting or sustaining human life **AND** the device does **NOT** present a potential for serious risk to the health, safety, or welfare of a subject. |
|  | • The device is **NOT** intended for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health, **OR**  • The device is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health **AND** the device does **NOT** present a potential for serious risk to the health, safety, or welfare of a subject. |
|  | The device does **NOT** otherwise present a potential for serious risk to the health, safety, or welfare of a subject. |
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| 1. SIGNIFICANT RISK DEVICE STUDY (Check if “Yes”.) | |
|  | The device does not meet all of the above criteria. |
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| 1. RATIONALE (List the name of the device and provide details about why #1 or #2 was selected.) | |
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