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| --- | --- |
| **IRB Number:** |  |
| **Protocol Name:** |  |
| **Investigator:** |  |
| **Device Name:** |  |

|  |  |
| --- | --- |
| NON-SIGNIFICANT RISK DEVICE | |
|  | Is not intended as an implant and does not present a potential for serious risk to the health, safety, or welfare of a subject.  **Rationale:** |
|  | Is not purported or represented to be for a use in supporting or sustaining human life and does not present a potential for serious risk to the health, safety, or welfare of a subject.  **Rationale:** |
|  | Is not intended 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.  **Rationale:** |
|  | Otherwise does not present a potential for serious risk to the health, safety, or welfare of a subject. **Rationale:** |

**If the criteria above is not met, an IDE application must be submitted to the FDA.**