This checklist is used to determine and document whether an investigational device is not a significant risk device.

1. **Non-significant risk device** 21 CFR §812.3(m)
   - 1.1 The device is NOT intended as an implant that presents a potential for serious risk to the health, safety, or welfare of a subject.
   - 1.2 The device is NOT purported or represented to be for a use in supporting or sustaining human life that presents a potential for serious risk to the health, safety, or welfare of a subject.
   - 1.3 The device is NOT for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health that presents a potential for serious risk to the health, safety, or welfare of a subject.
   - 1.4 The device does NOT otherwise present a potential for serious risk to the health, safety, or welfare of a subject.

2. **Notes**