Protocol #: ***[ADD]***

Short Title: ***[ADD]***

Documentation of NSR Determination

Per 21 C.F.R. § 812.3(m), the FDA defines significant risk devices as those meeting the following criteria: (1) Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; (2) Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject; (3) Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or (4) Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

In consideration of ***[ADD DEVICE]***, it does not meet the above criteria, therefore may be classified as a Nonsignificant Risk Device. Our justification follows:

1. [***ADD*** *justification as to why your device is NOT classified as an implant and/or and presents a “potential for serious risk to the health, safety, or welfare of a subject.”*]
2. [***ADD*** *justification as to why your device is NOT used “in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject”]*
3. [***ADD*** *justification as to why your device is NOT “of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject*”]
4. [***ADD*** *justification as to why your device DOES NOT “present a potential for serious risk to the health, safety, or welfare of a subject*”]