DOCUMENTATION OF IRB APPROVAL:
MEDICAL DEVICE STUDIES-REGULATORY REQUIREMENTS CHECKLIST

IRB #_____ Principal Investigator: _____

Protocol Title: _____

Device: _____

In accordance with the regulations set forth in 21 CFR Part 812, the IRB considered both the device as well as the nature of harm that may result from the use of the device and arrived at the following conclusions:

1. ☐ The study sponsor has NOT classified the device as "significant risk".

2. ☐ There is NOT an IDE number available for the specific use of this device.

3. ☐ The device is NOT intended for use as an implant.

4. ☐ The device is NOT used for supporting or sustaining life.

5. ☐ The device does NOT have substantial importance in diagnosing curing, mitigating, or treating disease.

6. ☐ The device does NOT present a potential for serious risk to health, safety or welfare of subjects.

If any of the above statements cannot be met, the device study represents Significant Risk and an IDE number for the device is needed. The device study may not commence until the FDA approves the IDE and the IRB approves the device and informed consent document(s).

Final Determination:

☐ Non-Significant Risk Device

☐ Significant Risk Device

IRB Vice Chair: _____ Date: _____