**FORM 5.2A- RISK DETERMINATION - DEVICES**

**INVESTIGATOR: IDI REC #**

**STUDY TITLE**

|  |  |  |  |
| --- | --- | --- | --- |
|  | | **Yes** | **No** |
| Is the device intended as an implant? | |  |  |
| Does the device support or sustain human life? | |  |  |
| Is the device’s use of substantial importance in: diagnosing, curing, mitigating, or treating disease, or preventing impairment of health? | |  |  |
| Could the investigational device cause significant harm to any participants? | |  |  |
| Must participants undergo a procedure as part of the device study? | |  |  |
| Could the study or any of the study procedures cause harm the participants? | |  |  |
| Could be life threatening |  |  |  |
| Could cause permanent impairment of a body function |  |  |
| Could cause permanent damage to body structure |  |  |
| Could necessitate medical or surgical intervention to: | |  |  |
| -Preclude permanent impairment of a body function |  |  |  |
| -Preclude permanent damage to body structure |  |  |  |
| Does the study device appear on the NDA, FDA list of Significant Risk (SR) devices? | |  |  |
| Does this appear to be a non-significant risk (NSR) device study? | |  |  |

Comments:

Primary Reviewer Date