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| **STUDY TITLE** |       |
| **PI NAME** |       |

**Note: If the research involves more than one device, submit a form for each device.**

The following must be submitted with this form:

* Device Manual and/or Instructions for Use
* If the study involves an IDE, submit one of the following:
	+ Sponsor protocol imprinted with the IDE number
	+ Written communication from the sponsor documenting the IDE number
	+ Written communication from the FDA documenting the IDE number

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| --- | --- |
| **1.** | **Provide the following information:** |
| Name of Device |       |
| Manufacturer |       |
|  |
| **2.** | **Regulatory Status:** |
| **[ ]**  | 510 (k) (i.e., “substantially equivalent” to a marketed device). 510(k) #       |
| **[ ]**  | 510 (k) exempt under 21 CFR Part       |
| **[ ]**  | PMA (pre-market approval). PMA #       |
| **[ ]**  | Investigational (not approved for any indication) |
| **[ ]**  | Approved, but its use in this research is investigational |
|  |
| **3.** | **Device Classification** |
| **[ ]**  | I (e.g., bandages, examination gloves, hand-held surgical instruments) |
| **[ ]**  | II (e.g., wheelchairs, infusion pumps, surgical drapes) |
| **[ ]**  | III (e.g., replacement heart valves, silicone breast implants, implanted stimulators) |
|  |
| **4.** | **Describe the proposed use:**  |

If the device is approved/cleared and being used according to its approved indication, **STOP** and submit this form.

If the device is investigational or approved/cleared but its use in the research is investigational, answer the following:

|  |  |
| --- | --- |
| **5.** | **This device research should be determined to be (complete one):** |
| **[ ]**  | **Significant Risk** (SR) – (e.g., sutures, cardiac pacemakers, hydrocephalus shunts, orthopedic implants)a. Investigational Device Exemption (IDE) number:      b. State who holds the IDE (i.e., sponsor, investigator, other):       c. Describe the process for investigational device accountability, storage, and recordkeeping to ensure that the device will be used according to the approved protocol, under the direction of approved investigator(s).       |
| **[ ]**  | **Non-significant Risk** (NSR) – (e.g., daily-wear contact lenses, lens solutions, dental scalers, foley catheters)Provide supporting documentation from sponsor regarding why the device does not pose a significant risk. |
| **[ ]**  | **IDE Exempt**Category (1-7):      Explain how the device is exempt from the requirements of 21 CFR 812.2(c) for this research. |