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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

|  |  |  |  |
| --- | --- | --- | --- |
| **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. |