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| Device Form  For Clinical Investigations |
| **Name of Device:**Click or tap here to enter text.  **Use of Device**:  Has any other IRB reviewed and made decisions regarding this device? Yes  No  If yes, please explain: |
| **Section A: HUD**   1. Is this a Humanitarian Use Device (HUD)?   No, proceed to Section B  Yes  HDE Number  Holder of HDE  Confirmation via:  Sponsor protocol imprinted with the HUD  FDA Letter   1. Will the HUD be used only as described as per the FDA HDE-approved indication?   Yes 🡪 this may be regarded as non-research, but still requires IRB approval  No 🡪 will IDE be obtained?  Yes  No, please provide rationale for not obtaining an IDE:   1. Will the HUD be used solely for clinical care?   Yes  No   1. Will safety and/or effectiveness of the HUD be assessed?   Yes  No |
| **Section B: IDE**   1. Is there an IDE? To determine whether the device requires an IDE, review this [FDA Guidance](https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/investigational-device-exemption-ide)   Yes  No  5a. If Yes  IDE Number:Click or tap here to enter text.  Holder of IDE:Click or tap here to enter text.  Confirmation via:  Sponsor protocol imprinted with the IDE  FDA Letter  5b. If No:  Will device be used as per approved indication?  Yes:  Confirmation via:  Manufacturer insert  Other  Brand name(s):  No, please **ATTACH** documentation of exemption from requirement for an IDE submission AND explain the status of the Device with FDA: |
| **Section C: Risks**  Are the risks presented by this device  SIGNIFICANT or  NON-SIGNIFICANT? See [FDA Guidance](https://www.fda.gov/media/75459/download).  If non-significant, please provide rationale: |
| **Section D: Source of Device**  Sponsor Name:Click or tap here to enter text.  Non-sponsor Manufacturer, if applicable:Click or tap here to enter text.  Will the device be provided free-of-charge\*? Yes  No  **\*Please note that in-stock devices may not be used for HUD/IDE. All HUD/IDEs are labeled as such.** |
| **Additional Attachments**  Attach Instructions for Use (IFU)  Attach any and all Summary of Risk and Benefit document (from Sponsor) |
| **Authorized Prescribers (include any investigators listed on research):** |
| **In Case of Adverse Reaction, notify (list name and phone number):**  ***Principal Investigator:*** Click or tap here to enter text.  ***PI Designee:***Click or tap here to enter text.  ***Medical Director of Manufacturer:***Click or tap here to enter text. |