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| Device FormFor 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 [ ]  YesHDE NumberHolder of HDEConfirmation via:[ ]  Sponsor protocol imprinted with the HUD[ ]  FDA Letter1. 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[x]  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 YesIDE 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 Letter5b. If No:Will device be used as per approved indication?[ ]  Yes:Confirmation via:[ ]  Manufacturer insert[ ]  OtherBrand 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. |