

**Humanitarian Use Device Continuing Review Application**

**(Non-Research Use)**

|  |  |
| --- | --- |
| **Responsible Physician Name:** | **IRB #:** |
| Name of HUD: | HDE #: |

Please complete the following to update the IRB on local uses of the HUD and any new or updated information that may be available on the device.

1. How many times has the device been used locally since the initial IRB approval?

1. How many times has the device been used locally since the last IRB continuing review?

1. Please provide the following information regarding uses of the device that have occurred since the last continuing review (or, if this is the first continuing review, since the initial approval).
   1. Provide a brief synopsis describing each local use. Include: (1) age of patient, (2) indication for use, (3) overall tolerance, and (4) any adverse events or complications with a possible, probable, or definite relationship to the HUD use.

* 1. Were any of these uses for an indication outside of the FDA labelling and/or the indications previously approved by the IRB?

YES, describe:

NO

* 1. Did any local adverse events or complications occur that were unexpected given the known risk profile of the device and/or the patient’s underlying condition(s)?

YES, describe:

NO

* 1. Did use of the HUD cause or contribute to any local deaths?

YES

NO

* + 1. If YES, was the death reported to the IRB, HUD manufacturer, and the FDA?

YES. Date(s) reported to IRB: Manufacturer: FDA:

NO, explain:

* 1. Did use of the HUD cause or contribute to any serious injuries? *Serious injury means an injury or illness that (1) is life-threatening, (2) results in permanent impairment of a bodily function or permanent damage to a body structure, or (3) necessitates medical or surgical intervention to preclude permanent impairment of a bodily function or permanent damage to a body structure.*

YES

NO

* + 1. If YES, was the serious injury reported to the IRB and the HUD manufacturer?

YES. Date(s) reported to IRB: Manufacturer:

NO, explain:

* 1. Have there been any local complaints by patients or others about the HUD?

YES

NO

* + 1. If YES, was the complaint(s) reported to the IRB?

YES. Date(s) reported to IRB:

NO, explain:

* 1. Has the manufacturer provided you with any safety reports or summaries of data available about the device?

YES

NO

* + 1. If YES, were the reports submitted to the IRB?

YES. Date(s) reported to IRB:

NO, explain:

* 1. Since the last IRB review, has the manufacturer provided you with any updated product information or patient materials?

YES

NO

* + 1. If YES, were the updated materials submitted to the IRB?

YES. Date(s) submitted to IRB:

NO, explain:

* 1. Since the last IRB review, have there been any publications in the literature relevant to this HUD?

YES

NO

* + 1. If YES, (1) attach a reference list of all known relevant English-language publications to this submission and (2) provide a brief summary (either here or attached) of the relevant findings in the 5 most recent English-language publications):

**Include with this submission:** (check each applicable item)

Any previously unsubmitted Medical Device Reports.

Any previously unsubmitted complaints.

Any previously unsubmitted sponsor provided safety reports or summaries.

Any previously unsubmitted product information or patient materials.

The manufacturer’s most recent annual report to the FDA.

The currently utilized consent and/or patient information packet.

Any other new relevant information or materials. Describe: