

**Humanitarian Use Devices Initial Application (Non-Research Use)**

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

Per federal regulation, a Humanitarian Use Device (HUD) must undergo initial and continuing review by the facility’s IRB; unless the use is an emergency use, in which case the reporting and documentation requirements for emergency use must be followed.

If you are proposing to study the safety or effectiveness of the HUD, all of the applicable research regulations apply and submission of a complete application for IRB review including a fully-developed research protocol and subject consent form is required.

Please complete the following to describe your intentions regarding the proposed non-research use of the HUD and to provide the IRB with sufficient information to conduct its review.

1. Provide the following information regarding the providers who will use the HUD:

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| **Name, Degree** | **Clinical Practice Area(s) (e.g., Interventional Cardiology)** |
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2. List the facilities/locations where the HUD will be used:

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| **Facility Name/Location** |
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3. Describe precautions being taken to minimize the chances of device use by health care providers not listed on this application (special ordering requirements, labeling, separate stocking, etc.).

4. Provide the FDA-approved indications for the use of the HUD:

5. Describe the patient population for whom you intend to use the device:

Anticipated age range:

Anticipated number of patients to be treated at this/these facility/s per year:

6. Describe the indications for which you propose to use the device:

7. Describe any credentialing procedures and training in the use of the HUD that will occur prior to use:

8. Describe the known risks of the HUD and any mechanisms you intend to put into place to minimize those risks.

9. Are the indications for which you propose to use the device all approved indications (as described in the FDA approval order and product labeling)? [ ]  Yes [ ]  No

If no, describe the proposed off-label use(s), provide justification, and describe any potential change in risks:

11. Describe any screening procedures that you intend to use in order to determine whether the use of the device for an individual patient is appropriate.

12. Do you anticipate being able to provide information about the HUD to the patient prior to or after the device is used?

[ ]  Prior to use

[ ]  After, provide justification:

11. Describe how you will provide information about the HUD to the patient or their legally-authorized representative. (check all that apply)

[ ]  Oral Description

[ ]  Consent Document

[ ]  Manufacturer provided patient labeling and materials

[ ]  Other, describe:

12. Briefly describe how the patients will be monitored following device implantation or use (follow-up visits, tests or procedures).

Include with this submission:

[ ]  CVs for each credentialed and licensed provider proposed to utilize the HUD;

[ ]  Product training certificates for each credentialed and licensed provider proposed to use the HUD, if applicable;

[ ]  A copy of the HDE approval order from the FDA;

[ ]  The product labeling;

[ ]  Directions for use (if separate from the labeling);

[ ]  The patient information packet that may accompany the HUD;

[ ]  Proposed consent document (if applicable);

[ ]  Any other patient or product materials. Describe:

**Note:** Additional institutional approvals, such as the approval of supply chain, may be necessary. The provider listed on this application is responsible for ensuring that all institutional approvals are in place and that all applicable policies and procedures are adhered to.

**Note:** HUDs are subject to Medical Device Reporting Requirements as follows. It is the responsible physician’s responsibility to ensure that these requirements are satisfied.

*User facilities (i.e., the Responsible Physician) must submit reports to FDA, the IRB of record, and the manufacturer whenever a HUD may have caused or contributed to a death, and must submit reports to the manufacturer (or to FDA and the IRB of record if the manufacturer is unknown) whenever a HUD may have caused or contributed to a serious injury (21 CFR 803.30 and 814.126(a)). 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 (21 CFR 803.3). The specific requirements for this reporting are set forth in the Medical Device Reporting (MDR) Regulation, at 21 CFR Part 803.*