# Revision History

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| --- | --- | --- |
| **Requestor** | **Change(s)** | **Date** |
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|  |  |  |

Basic Details

1. What is the title of this application? [PULL; NOT EDITABLE]
2. Treatment Location [PULL; NOT EDITABLE]
3. Describe the device and the indication for use approved by the FDA. Include information on previous use. [PULL; NOT EDITABLE]
4. Staff List

Renewal Application

1. How many times has the device been used in the past year?
2. Have any unanticipated problems occurred in the past year?

**If yes**,

1. Please describe.
2. Has there been any change in the FDA approval status of the device?

**If yes**,

1. Please describe.

Staff

Please list the Treating Physician, as well as personnel obtaining clinical consent and/or assent.

[PULL FROM INITIAL APPLICATION; NOT EDITABLE]

If this information needs to be updated, you must submit a Modification prior to submitting the Renewal Application.

Documents

Review and Submit

I certify that the information provided in this request is complete and accurate. I agree to:

* perform the procedure as outlined herein and approved by the IRB;
* use the device only as described on the FDA approved label;
* provide the patient with appropriate information to make an informed decision about the use of the device;
* report unanticipated problems involving risk to patients to the IRB according to IRB procedures;
* notify the patient of any new findings regarding the device.

I certify that the HUD is not being used as part of a research project or clinical investigation designed to collect data to support an FDA pre-marketing approval application.