

Note (0 Notes Total)

01-5. Humanitarian Use Device

Completion of this section is required based on the response provided to question 1-1.1.

1-5.1* What is the name of the device? Include the generic and trade names as applicable.

Type generic and trade name of the device here.

1-5.2* What is the source (supplier or manufacturer) of the device?

Type the name of the manufacturer of the device here.

1-5.3* What is the indication for use of the device?

This information should be provided to you from the manufacturer. It must be the same information that the FDA received in issuing the HDE.

1-5.4* What are the alternative practices and procedures?

If there is other clinical care/standard care other than this device explain that here. If there are no alternative practices or procedures, so state.

1-5.5* What is the proposed mechanism of action of the device? Describe the device and include any post-manufacturing modifications to the device.

Describe.

1-5.6* What is the frequency and total duration of use of the device?

Explain the use.

1-5.7* What are the contraindications, warnings, and precautions for the use of the device?

This information should be provided to you by the manufacturer.

1-5.8* Describe any foreseeable adverse effects of the device.

This information should be provided to you by the manufacturer.

The risk designation for 1-5.9 should also come from the manufacturer.

1-5.9* What is the sponsor's risk designation for the device


Select one:

Non-significant Risk (NSR)

Significant Risk (SR)

[Clear](#)

1-5.10* Date of HUD designation:

8/1/2007 



1-5.11* HDE number:

This number must be accurate. Manufacturer should supply it.

1-5.12* Attach the Humanitarian Device Exemption (HDE) documentation as provided by the sponsor:

[Add](#)


[Delete](#)

Name	Version
<input type="checkbox"/> [Edit] HDE doc 	0.01
<input type="checkbox"/> [Edit] Include any labelling and Package Insert Info 	0.01

1-5.13* Upload the unsigned informed consent document (to protect patient privacy) here:

[Add](#)

[Delete](#)

Name	Version
<input type="checkbox"/> [Edit] Consent Doc 	0.01

1-5.14* Affirm that the use of the HUD as described in this application will not contribute data to any ongoing research project or clinical investigation.