01-5. Humanitarian Use Device

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

Hide

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

Note: For Dental School Applications, See Help for more information.

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

List the main manufacturer of the HUD. Fo example, if Medtronics provides the HUD, has subcontracted aspects of the device's manufacture, you would list Medtronics as source of the device. If the device is house and dispensed from the OR, you would sti Medtronics as the source of the device.

Additional Help

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

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

If there are no alternative practices or procedures, so state.

Additional Help

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.

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

Exit Save Continue

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

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

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:

1-5.11* HDE number:

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

+ Add

Name	Version
There are no items to display	

Additional Help

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

+ Add

Name	Version
res_irbmed_IRBMED-HUD-consent(0.02) •••	0.02

Additional Help

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.

☐

This does not preclude reporting any FDA-required information to the manufacturer o sponsor of the HUD.