Guidance for Investigators: Humanitarian Use Device (HUD) Decision Tree

1. Is the HUD use necessary to prevent death or serious harm to a patient?
   - Yes: Follow procedures for emergency use of the HUD.
   - No: IRB review of application for use of the HUD in the facility.

2. Is the HUD to be used for HDE-approved indication(s) only?
   - Yes: Use safety or effectiveness data to be collected?
     - Yes: The HUD use is a clinical investigation. 21 CFR Part 50 and 21 CFR Part 56 apply; no IDE is required for study of approved indication(s).
     - No: The HUD use is not a clinical investigation.
   - No: Is the HUD being used as part of a clinical investigation?
     - Yes: The HUD use is a clinical investigation. 21 CFR Part 50 and 21 CFR Part 56 apply; IDE regulations at 21 CFR 812 apply.
     - No: The IRB review process is up to the IRB; IRBs should be cognizant that FDA has made a determination of safety and probable benefit for use of the HUD only within its approved indication(s).