

## **Humanitarian Use Device (HUD)**

As defined in 21 CFR 814.3(n), a HUD is a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. A HUD application is similar to a premarket approval (PMA) application, but is exempt from the effectiveness requirement of sections 514 and 515 of the act. The application, however, must contain sufficient information for FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury from its use.

In accordance with 21 CFR 814.102(a), a HUD request must include the following:

- A statement indicating you are requesting a HUD designation
- The name and address of the applicant
- A description of the disease or condition for which the device is intended
- A description of the device
- Documentation, with appended authoritative references, to demonstrate that the device meets the definition of 21 CFR 814.3(n)

FDA approval of your HDE authorizes you to make your Humanitarian Use Device (HUD). However, a HUD may only be used after the institution's IRB has reviewed and approved the use of the device at the institution. The IRB's responsibility in this case is to conduct a special limited review simply to verify that the proposed use of the device is consistent with the HDE's FDA-approved indication. Informed consent of patients is not required because the use of the HUD in a manner consistent with its marketing approval under the HDE does not constitute research.

Guidance for Industry and FDA Staff - Humanitarian Device Exemption (HDE) Regulation: Questions and Answers:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071473.htm>