

[Open Peer Review on Qeios](#)

Humanitarian Device Exemption

National Cancer Institute

Source

National Cancer Institute. *Humanitarian Device Exemption*. NCI Thesaurus. Code C80440.

A premarket submission to FDA for a device intended to benefit patients by treating or diagnosing a condition affecting fewer than 4,000 individuals in the United States per year. An HDE is similar in form and content to a premarket approval (PMA) but is exempt from the effectiveness requirements of a PMA.