FDA seeks input on humanitarian device applications

Mass Device

The FDA seeks comments on a proposed collection of information, regarding humanitarian device exemption applications.



The FDA this week released new information to accompany humanitarian device exemption applications and related requirements.

The new guidelines build on <u>an announcement the FDA issued last year</u> [1], detailing the process for classifying a product as a humanitarian use device.

The humanitarian use device program applies to devices that diagnose or treat diseases and conditions affecting fewer than 4,000 people in the U.S. per year.

Source URL (retrieved on 03/10/2014 - 6:40pm):

 $\frac{http://www.mdtmag.com/news/2012/12/fda-seeks-input-humanitarian-device-applications?qt-video_of_the_day=0\&qt-recent_content=0$

Links:

[1] http://www.massdevice.com/news/fda-guidance-how-win-humanitarian-use-device-designation