FDA solicits comment on custom device review

Mass Device

The FDA opens up for public comment its custom medical device review protocols, asking interested parties to offer perspective on a system that has had some recent snafus.

The FDA is seeking public comment on its custom medical device exemption criteria following some changes implemented through the FDA Safety & Innovation Act, which was signed into law earlier this year.

The proposed rules include 4 main tenets for fitting the definition of a custom medical device as well as limits on annual production and use.