FDA wants stricter safety rules for pelvic mesh

29 April 2014

Makers of trouble-prone implants used to surgically repair women's pelvic problems would be subject to stricter safety requirements under a federal proposal issued Tuesday.

The Food and Drug Administration says plastic mesh used to repair pelvic collapse should be reclassified as a high-risk medical device, following years of reports of pain, bleeding and infection among women who have received the implants. If finalized, the change would require manufacturers to prove that their mesh products are safe and effective before they can be sold.

The proposal comes nearly three years after the agency concluded that women getting mesh have more complications than women who undergo traditional surgery with stitches. Mesh products were initially viewed as a high-tech improvement to surgery, but FDA said there is no evidence they improve safety outcomes.

APA citation: FDA wants stricter safety rules for pelvic mesh (2014, April 29) retrieved 2 May 2021 from https://medicalxpress.com/news/2014-04-fda-stricter-safety-pelvic-mesh.html