FDA sets new rules for injury-prone pelvic mesh

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Mesh implants used to repair pelvic collapse in women will face new federal scrutiny, under rules responding to thousands of injuries reported with the problem-prone devices.

The Food and Drug Administration says makers of pelvic mesh must submit data showing the safety of their products, following years of reports of pain, bleeding and infection among women receiving the implants. The new requirements do not apply to mesh products used to treat conditions like hernias or incontinence.

The FDA action comes more than four years after the agency concluded that women getting vaginal mesh have more complications than women who undergo traditional surgery with stitches. Mesh products were introduced for pelvic repair in the 1990s as a high-tech improvement to surgery, but FDA said there is no evidence they improve outcomes.