FDA orders safety studies of women's surgical mesh

4 January 2012

(AP) -- The Food and Drug Administration is ordering medical device manufacturers to study safety complications with surgical mesh widely used to repair women's pelvic problems.

The announcement follows an April FDA report which found that women who have the surgical mesh implanted to support their reproductive organs are at greater risk of pain, bleeding and infection than women who have traditional surgery with stitches.

The FDA said in an online post that 33 manufacturers of medical mesh would be required to submit follow-up safety studies to the agency. Manufacturers include Johnson & Johnson, Boston Scientific Corp. and CR Bard.

The FDA is considering reclassifying the mesh as a high-risk device, so that manufacturers would have to prove the product's safety and effectiveness before it could launch. The reclassification could take years.