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QUOTED. April 24, 2019. Jeff Shuren.

by

Boston Scientific and Coloplast have two more days until they have to submit plans to the US FDA outlining how they will recall their unimplanted transvaginal mesh after the agency ordered it yanked from the market. See what device center Director Jeff Shuren said about the mesh here.

"In order for these mesh devices to stay on the market, we determined that we needed evidence that they worked better than surgery without the use of mesh to repair POP [pelvic organ prolapse]. That evidence was lacking in these premarket applications, and we couldn't assure women that these devices were safe and effective long term." – Jeff Shuren, director, FDA's Center for Devices and Radiological Health

- Find out more: *FDA Yanks Transvaginal Mesh From US Market; Boston Sci 'Surprised'*