

## Robotically assisted surgical device authorized for transvaginal hysterectomy

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benign conditions. All 30 procedures were successfully completed with the Hominis Surgical System, and none required conversion to an open or other <u>laparoscopic surgery</u>. Reported adverse events included minor blood loss, <u>urinary tract</u> <u>infection</u>, and delayed healing at the vaginal cuff.

Marking authorization was granted to Memic Innovative Surgery Inc. The FDA is requiring the manufacturer to develop and provide a <u>training program</u> for surgeons and operating room staff to complete before operating the device.

**More information:** More Information

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A novel robotically assisted surgical device for transvaginal hysterectomy has received marketing authorization approval, the U.S. Food and Drug Administration announced Monday.

The Hominis Surgical System is approved for use in benign hysterectomy with salpingo-oophorectomy, providing a minimally invasive option for noncancerous conditions. The system uses minimally invasive surgical instruments inserted through the vagina and a video camera that is inserted laparoscopically through a small incision in the abdomen. According to the manufacturer, the surgical robotic platform has miniature humanoid-shaped robotic arms and biomimetic instruments designed to mimic the capabilities and motions of a surgeon's arms.

The approval was based on safety and effectiveness data from 30 patients with varying age, body mass index, and comorbidities who underwent transvaginal total hysterectomy with salpingo-oophorectomy or salpingectomy for



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