Robotically assisted devices not approved for cancer surgery

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(HealthDay)—The use of robotically assisted surgical devices for breast

removal and other cancer-related surgeries is not approved by the U.S. Food and Drug Administration because there is no proof of its safety or effectiveness in such cases, the agency says in a warning to doctors and patients.

"Certain patients with cancer may require surgical procedures to treat or prevent the spread of cancer in their body. These procedures are often associated with improved survival outcomes for these patients," Terri Cornelison, M.D., assistant director for the health of women in the FDA Center for Devices and Radiological Health, said in an agency news release. "However, today we are warning patients and providers that the use of robotically-assisted surgical devices for any cancer-related surgery has not been granted marketing authorization by the agency, and therefore the survival benefits to patients when compared to traditional surgery have not been established."

Robotically assisted surgical devices are used to perform a variety of surgical procedures through small incisions, and this type of surgery may help reduce pain, blood loss, scarring, infection, and recovery time.

However, in "the case of robotically-assisted surgical devices and cancer-related uses such as mastectomy, we are aware of scientific literature reporting that surgeons have been using the device for uses not granted marketing authorization by the FDA," Cornelison said. "We want doctors and patients to be aware of the lack of evidence of safety and effectiveness for these uses so they can make better informed decisions about their cancer treatment and care."

More information: More Information