FDA clears 3rd silicone-gel breast implant for US

MATTHEW PERRONE - AP Health Writer - Associated Press

The Food and Drug Administration has approved a new silicone-gel breast implant from Sientra, making it the third company to market the controversial products in the U.S.

Santa Barbara, Calif.-based Sientra won approval to market its implants for breast enhancement and reconstruction in women at least 22 years old. The company said it will offer implants in multiple shapes and sizes, in addition to the round implants currently sold by Allergan Inc. and Johnson & Johnson's Mentor unit.

Last year, plastic surgeons performed more than 307,000 breast augmentation procedures in the U.S., up 3.6 percent from the previous year, according to the American Society of Plastic Surgeons.

The FDA has wrestled with the safety of silicone-gel implants for more than 20 years. In 1992, the agency banned the products amid fears they might cause cancer, lupus and other diseases. But when research ruled out most of the disease concern, regulators returned the implants to the market in 2006.

Since then the FDA has required manufacturers to track the health and complications of women who receive the implants. The most recent data from Allergan and J&J confirm that the devices are prone to rupture and often need to be replaced.

More than one in five women who get implants for breast enhancement will need to have them replaced within five years, accord to an FDA analysis of company data released last summer. Despite that relatively high failure rate, FDA regulators concluded that the silicone-gel implants are basically safe as long as women understand they come with complications. Some critics of the implants say the failure rate may be even higher, since many women have dropped out of the company studies.

Problems with rupturing and scar tissue are also seen with saline-filled versions of breast implants, which are less popular. Many women prefer silicone implants because they generally look and feel more like natural breast tissue.

Sientra will be subject to the same FDA-mandated requirements to track patients and report safety information back to the agency.

The privately held company, founded in 2007, specializes in plastic surgery implants, including those for the face, legs and buttocks.

"Sientra has successfully broken the existing duopoly in the U.S. by offering surgeons and patients a new choice," said CEO Hani Zeini, in a statement.

Allergan Inc. is based in Irvine, Calif., and Mentor, a unit of Johnson & Johnson, is based in Santa Barbara.