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FDA approves Montco firm's weight-loss device

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John George

The Food and Drug Administration has approved an obesity treatment device, developed by a Montgomery County company, that uses a surgically placed tube to drain a portion of the stomach contents after every meal.

Aspire Bariatrics of King of Prussia, Pa., has spent the past six years developing its AspireAssist device and already sells it in some European countries.

"This is a huge deal for us," said Katherine D. Crothall, the CEO of Aspire, of the FDA's approval. "This opens us up to the largest market for obesity devices, which is the United States. The second thing it does is add credibility to our product and procedure. It's fair to say worldwide the medical community looks at the FDA as having the most rigorous approval process. The assumption is if the FDA approves a product it's safe and effective. This will help us in the United States and outside the United States as well."

Crothall said AspireAssist provides patients with a body mass index above 35 with a less invasive and reversible alternative to bariatric surgery procedures that reduce the size of a person's stomach.

In approving the device, the FDA said it should not be used on patients with eating disorders, and it is not intended to be used for short durations in those who are moderately overweight. The federal agency said AspireAssist is intended to assist in weight loss in patients aged 22 and older who are obese, with a body mass index of 35 to 55, and who have failed to achieve and maintain weight loss through nonsurgical weight-loss therapy.

"The AspireAssist approach helps provide effective control of calorie absorption, which is a key principle of weight management therapy," said Dr. William Maisel, deputy director for science and chief scientist in the FDA's Center for Devices and Radiological Health. "Patients need to be regularly monitored by their health care provider and should follow a lifestyle program to help them develop healthier eating habits and reduce their calorie intake."

Here is how the Aspire Assist works:

A surgeon inserts a tube in the stomach with an endoscope via a small incision in the abdomen. A disk-shaped port valve that lies outside the body, flush against the skin of the abdomen, is connected to the tube and remains in place. About 20 to 30 minutes after meal consumption, the patient attaches the device's external connector and tubing to the port valve, opens the valve and drains the contents. Once opened, it takes five to 10 minutes to drain food matter through the tube and into the toilet. The device removes about 30 percent of the calories consumed.

Earlier this month, Aspire Bariatrics **raised $3.6 million** through the sale of convertible notes in anticipation of its U.S launch of the device.

Crothall said at that time her company plans to hire a U.S. sales staff to promote the device to gastroenterologists and bariatric surgeons, and to hire other personnel to work with health insurance companies to get the treatment reimbursed. “We will probably be adding 10 to 12 people,” Crothall said. Aspire currently employs 18 workers.

Crothall said Tuesday the company will now work with hospitals and outpatient centers to make the device available to patients as soon as possible.

The FDA approved the device after reviewing results from a clinical trial of 111 patients treated with AspireAssist and appropriate lifestyle therapy, which includes nutrition and exercise counseling, and 60 control patients who received only the lifestyle therapy. After one year, patients using AspireAssist lost an average of 12.1 percent of their total body weight compared to 3.6 percent for the control patients.

The study also identified side effects related to use of the AspireAssist that include occasional indigestion, nausea, vomiting, constipation and diarrhea.