

Mesa firm gets FDA approval on ultrasound device

A Mesa startup company has developed a medical device that uses ultrasound technology to treat everything from sagging eyebrows to liver cancer.

Guided Therapy Systems of Mesa said the device allows doctors to see and treat tissue without using traditional surgery.

The device will be used initially for cosmetic purposes, but backers say the technology has the potential to treat tumors without invasive surgery.

Ulthera Inc., a Mesa-based spinoff of Guided Therapy, gained Food and Drug Administration approval in September to market the device for cosmetic facial treatment. The company now is building its sales staff to market the device to cosmetic dermatologists and plastic surgeons.

"The idea is I can push a button and use concentrated energy to destroy tissue," said Michael Slayton, founder and chairman of Guided Therapy Systems and Ulthera. "In other words, it is a non-invasive scalpel."

Similar technology is being tested nationwide by other startups in the United States and Europe because it employs focused energy beneath a person's skin to tighten wrinkles, zap fat or attack tumors.

Ulthera has started to sell the device to plastic surgeons and dermatologists for procedures such as eyebrow lifts and facial tightening. The company has raised about \$30 million, hired more than 20 employees and plans to double in size next year.

Guided Therapy has a second spinoff company, Xthetix, which is developing a handheld device for consumers that can be used to treat acne and rejuvenate skin.

Company representatives are encouraged by the FDA clearance, which they believe gives the firm an advantage over other firms developing ultrasound-based treatments.

"This is the first technology that the agency (FDA) has determined to be safe," said Brian O' Connor, president and chief operating officer of Guided Therapy.

Other companies are seeking to gain FDA approval for similar technology.

Liposonix, which was acquired by Scottsdale-based Medicis last year, is seeking FDA approval for its ultrasound technology used to bust fat beneath the skin. The technology has been cleared for commercial sale in Canada, but Medicis has not yet received the green light to market the device in the United States. Medicis has started clinical trials with the goal of gaining FDA approval by 2011.

O'Connor said Guided Therapy plans to further develop the technology for other medical and aesthetic purposes, including areas such as women's health, sports medicine and oncology.

Guided Therapy previously developed the technology in tandem with Ethicon Endo-Surgery, a suburban Cincinnati subsidiary of Johnson & Johnson. Ethicon and Guided Therapy spent millions to develop the product as a treatment for a type of liver cancer, O'Connor said, but ultimately dropped the product because the company believed there was a limited market.

Guided Therapy representatives said cosmetics is a logical industry to launch the device due to consumer demand as well as the lack of red tape associated with insurance reimbursement. If people want the treatment, they must pay cash and typically have the financial means to do so.

Slayton said the cosmetics field represents "a means to an end" as the company develops the device for medical purposes.

Pitching the device

Still, there is no guarantee that the device will catch on among cosmetic dermatologists and their customers.

"Consumers love new things, love safety and love the idea of using energy," to tighten skin, said Dr. Susan Van Dyke, a cosmetic dermatologist in Paradise Valley. "The proof is in the results."

Van Dyke said her office now uses a technology known as "thermage" that uses radio frequency to tighten facial skin. She said the ultrasound-based technology would have to prove to be "quite a bit better" than existing technology for her office to take the plunge and purchase such a system.

Matthew Likens, president and chief executive officer of Ulthera, said early demand for the company's device has been robust. The list price is \$89,000, but Likens said "early adopters" can get a discount. It's up to dermatologists to set pricing for consumers.

"It's not a hard sell," Likens said. "People want to look and feel better about themselves."

Mark Henle/The Arizona Republic

Randall E. Miller demonstrates a device on Teri Larson. Guided Therapy Systems of Mesa said the device allows doctors to see and treat tissue without using traditional surgery

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