



PRESS RELEASE

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ULTHERA RECEIVES FIRST-EVER FDA CLEARANCE TO MARKET ULTRASOUND TECHNOLOGY FOR FACIAL AESTHETIC IMPROVEMENT

New DeepSEE™ Ultrasound for Non-invasive Lift

Mesa, AZ - (September 16, 2009) /PRNewswire/ — Ulthera, Inc., a therapeutic ultrasound medical device company serving the \$30 billion global aesthetics market, today announced that the U.S. Food and Drug Administration (FDA) has granted clearance for the use of its Ulthera™ System to achieve a non-invasive eyebrow lift.

The Ulthera System is considered a first-of-its-kind technology, unprecedented in the marketplace, and as such underwent a 510(k) "de novo" review by the FDA. It is substantially different than other in-office aesthetic devices because it combines visualization beneath the skin's surface with non-invasive delivery of ultrasound energy at depths that enable significant lifting of the skin. While drawing on the same reliable ultrasound principles that physicians and patients have trusted for decades, Ulthera's patented DeepSEE™ technology allows physicians in aesthetics to both see and treat deep below the skin without surgery.

"We use imaging to anticipate where the energy will be placed, and then we deliver small amounts of very productive energy to targeted planes of tissue. This precision contributes to both safety and effectiveness, and because this is accomplished without damaging the superficial layers of skin, patients experience no down time," said principal investigator Murad Alam, M.D., Associate Professor of Dermatology and Otolaryngology and Surgery, and chief of the Section of Cutaneous and Aesthetic Surgery at Northwestern University's Feinberg School of Medicine.

Focused ultrasound energy triggers the body's natural healing response, resulting in new and improved collagen support and gradual firming, tightening and actual *lifting* of skin tissue over time. Patients receiving an Ultherapy treatment for a brow lift, for example, report less hooding and laxity of the eyelid skin and a more "open" look around the eyes, contributing to a more refreshed look overall. Outside the United States clinicians have begun performing Ultherapy using a "dual plane" approach to create significant improvements in the lower face and neck. In one procedure patients are treated at two different depths, affecting twice the volume of tissue. Unlike other energy-based treatments used for skin tightening, Ulthera's non-invasive approach is yielding consistent, significant changes.

Extensive pre-clinical studies were conducted at multiple sites beginning in 2004. Subsequent patient clinical trials beginning in 2006, consisting of full-face procedures, yielded safe, reproducible and clinically significant lift with no recuperation time.

"Ultherapy represents a new category of treatment that strikes a noteworthy blend of both safety and effectiveness," said Matt Likens, President and CEO of Ulthera. "We are excited that our safe, non-invasive procedure has produced such reliable results. The eyebrow lift indication is just the first of a multitude of cosmetic and medical indications the Company will pursue for this platform technology."

The Company received its CE Mark in 2008 and began commercialization activities outside the U.S. late last year. Health Canada clearance was achieved on May 6, 2009, and Ulthera currently markets the Ulthera™ System in Canada, Australia, Asia, Europe and the Middle East. FDA clearance qualifies the System for sale in additional key aesthetics markets such as South Korea, Thailand, Taiwan and others.

Ulthera will be marketing the Ulthera System directly to dermatologists, plastic surgeons and facial plastic surgeons in the U.S., while partnering with a network of international distributors outside the U.S. The measured roll-out of the system will be accompanied by comprehensive technical and clinical support to ensure the highest standard of customer and patient satisfaction.

About Ulthera

Ulthera, Inc. develops and markets innovative medical devices that leverage the proven power and safety of ultrasound for rejuvenation of the skin and its support structures. Treatment with the Ulthera System enables dermatologists, plastic surgeons and facial plastic surgeons, for the first time, to non-invasively see and treat at prescribed depths below the skin's surface, resulting in significant, reliable outcomes. Ulthera's technologies and clinical standards meet or exceed all FDA benchmarks for safety and effectiveness, and are rooted in rigorous, ongoing clinical and scientific research.

Ulthera is privately held and headquartered in Mesa, Arizona. It was founded in 2004 and was the first company to be spun off from Guided Therapy Systems, LLC, a Mesa, Arizona-based ultrasonic medical technologies company. Ulthera is supported by venture capital funding provided by New Enterprise Associates (NEA) in the U.S. and Apposite Capital LLP., from the UK. For more information, please visit www.ulthera.com.

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