



ULTHERA ANNOUNCES TWO YEAR FDA CLEARANCE FOR CELLFINA™ SYSTEM

Cellfina™ Earns Longest FDA Clearance for a Cellulite Treatment

RALEIGH, N.C. – AUGUST 3, 2015 – BUSINESS WIRE – Ulthera, Inc. a wholly-owned subsidiary of Merz, Inc. (US affiliate of the global Merz Pharma Group), announced today that the U.S. FDA has cleared its [Cellfina™ System](#) for the long-term improvement in the appearance of cellulite on the buttocks and thighs with no loss of benefit for up to 2 years.

“When Merz acquired Ulthera in June 2014, we recognized that our organizations have a shared mission: to bring innovations to market that meet the needs of physicians and improve the well-being of patients,” said Bill Humphries, President and CEO of Merz North America. “This shared long-term vision has enabled the seamless integration of Ulthera into Merz’s business operations over the past year and provides us with a solid foundation to launch additional innovative technologies such as the Cellfina™ System.”

“As the newest addition to Merz’s growing aesthetic portfolio, Cellfina™ has quickly established a strong reputation among patients and physicians alike as an effective, minimally-invasive way to treat cellulite with long lasting results,” said Patrick Urban, Vice President and Head of the Ulthera® Business Unit at Merz North America. “As we prepare for the full commercial launch of Cellfina™ in the U.S., we remain committed to partnering with physicians in order to deliver outcome-focused innovation and a better total experience in aesthetics.”

Cellfina™ is the only FDA-cleared minimally invasive procedure clinically proven to improve the appearance of cellulite for results that last at least two years, the longest duration cleared by the FDA. The Cellfina™ System combines highly advanced, proprietary technology with a well-established procedure called subcision, to treat the primary structural cause of cellulite.

“In my practice, Cellfina™ has become the gold standard for treatment of cellulite on the thighs and buttocks,” stated [Dr. Grant Stevens](#), Clinical Professor of Surgery at the University of Southern California’s Division of Plastic & Reconstructive Surgery. “I am confident that the FDA’s recent clearance of Cellfina™ for safe, effective results lasting up to two years will prove critical in helping physicians feel confident in recommending this single, minimally-invasive procedure to their patients.” A board-certified plastic surgeon in private practice at Marina Plastic Surgery in Marina Del Rey, California, Dr. Stevens, who has been voted one of the Top Plastic Surgeons in the U.S., also serves as the Director of the USC – Marina Del Rey Aesthetic Surgery Fellowship and the Co-Director of the USC Aesthetic Surgery Division.

Merz North America
Mariana Smith Bourland
Corporate Communications
6501 Six Forks Road
Raleigh, NC 27615
Phone (336) 339-0172
Mariana.Smith@merz.com
www.MerzUSA.com

“One of the most remarkable aspects of cellulite treatment with Cellfina™ is the extremely high rate of patient satisfaction over time,” stated [Dr. Michael Kaminer](#), Associate Clinical Professor of Dermatology, Yale Medical School. “Our clinical data shows that patient satisfaction with the results of Cellfina™ treatment improved from 94% at one year to 96% patient satisfaction at the two year mark, and my work in treating my own patients continues to support these results.” A board-certified dermatologist in private practice in Boston, Massachusetts, Dr. Kaminer is known as a leader, innovator and talented dermatologic surgeon and laser medicine expert. He is one of the three founding partners of SkinCare Physicians, a 15 physician, 100 employee group in Boston that is recognized as a world leader in medical and aesthetic dermatology.

In a prospective, multicenter US clinical study, 55 patients underwent a single treatment. The Cellfina™ System improved the appearance of cellulite in 98% of treated patients at two years, according to independent physician evaluators. Importantly, 96% of patients reported satisfaction with their treatment at the two year mark, and noticeable improvement on the Global Aesthetic Improvement Scale (GAIS) was seen in 100% of treated patients at two years. Most adverse events were treatment site reactions such as bruising, soreness and hemosiderosis, which were usually mild to moderate and short in duration (lasting about 2 weeks). No severe device-related adverse events were reported that required treatment.

The Cellfina™ System will be available to physicians across the U.S. in Fall 2015.

About Ulthera

Ulthera is an affiliate of Merz North America, a specialty healthcare company that develops and commercializes treatment solutions in aesthetics, dermatology and neurosciences in the U.S. and Canada. Ulthera’s signature technology is the Ulthera® System, which is FDA-cleared for use as an aesthetic ultrasound treatment – the Ultherapy® procedure – to non-invasively lift skin on the neck, under the chin and on the eyebrow as well as to improve lines and wrinkles of the décolleté. Ulthera is also launching the Cellfina™ cellulite procedure, an FDA-cleared treatment intended for the long-term improvement in the appearance of cellulite in the buttocks and thigh areas of adult females. For more information on Ultherapy® and Cellfina™, please visit www.ultherapy.com and www.cellfina.com.

For full product and safety information, including possible mild side effects of Ultherapy® and Cellfina™, visit www.ultherapy.com/IFU or www.cellfina.com/IFU.

Corporate Contact:

Mariana Smith Bourland
Corporate Communications
Merz North America

6501 Six Forks Road
Raleigh, NC 27615
Cell (336) 339-0172
Mariana.Smith@merz.com