

Miramar Labs, Inc.® Receives U.S. FDA 510(k) Clearance for Reduction of Odor

miraDry® system now FDA cleared to treat bothersome underarm sweat, hair and odor

SANTA CLARA, Calif., Nov. 07, 2016 (GLOBE NEWSWIRE) -- Miramar Labs, Inc., (OTCQB:MRLB), a global aesthetic company, announced today that it has received U.S. Food and Drug Administration (FDA) 510(k) clearance to market for reduction of odor when patients are treated with the miraDry system. miraDry is now the first and only FDA cleared device for the non-invasive treatment of odor.

Mike Kleine, Chief Executive Officer of Miramar, said, “FDA clearance for odor reduction is a significant milestone in our product development strategy that further enhances the value proposition of the miraDry system for aesthetic practices. We believe it will allow our customers to expand the appeal of the miraDry procedure with the same easy-to-use, safe and effective system that treats underarm sweat and hair. We look forward to introducing this new labeling into the market and continuing to advance our other new product programs, including expanding the miraDry technology for use in hand sweat.”

“miraDry is proven to reduce underarm sweat by delivering localized heat to the area where the eccrine sweat glands reside, and in many patients we have observed that the device also thermally impacts and eliminates the apocrine glands that are responsible for bad body odor,” said E. Victor Ross, MD, director of the Laser and Cosmetic Dermatology Center at Scripps Clinic in San Diego, Calif. “It is important to our patients that we not only treat their sweat, but that we also significantly decrease the odor-causing secretions that are often more noticeable and disturbing.”

Miramar Lab's proprietary miraWave® technology – use of precisely controlled microwave energy – is the foundation of the miraDry system. This latest FDA clearance builds on the miraDry System’s existing indications for the treatment of underarm sweat and for the permanent reduction of unwanted underarm hair of all colors.

About Miramar Labs:

Miramar Labs, Inc.® is a global medical device company dedicated to bringing innovative and clinically proven applications to treat unmet needs in the aesthetic marketplace. Supported by rigorous clinical research, Miramar Labs is focused on addressing medical conditions for which there are significant unmet clinical needs. The company’s first priority is the treatment of bothersome underarm sweat, an issue that hundreds of millions of people deal with daily. The miraDry® procedure has an established safety and efficacy profile with over 80,000 patients treated worldwide. Physicians and patients are encouraged to visit www.miramarlabs.com or www.miradry.com for additional information.

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