

ThermiAesthetics Announces FDA Clearance for ThermiRF Temperature Controlled Radio Frequency

ThermiRF creates new technology category for aesthetic applications – thermistor-regulated energy delivery for both micro-surgical and non-invasive aesthetic applications

Southlake, Texas November 20, 2013

ThermiAesthetics, creator of ThermiRF temperature controlled radio frequency system, received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for dermatological and general surgical applications in soft tissue and nerves. ThermiRF is the first aesthetic technology, which applies the “science of heat” using temperature as a clinical endpoint, enabling plastic surgeons and aesthetic physicians to precisely heat soft tissue and nerves to achieve desired aesthetic outcomes. ThermiRF is also the first aesthetic device to deploy simultaneous dual monitoring of tissue temperature (internal and external) using advanced infrared imaging for precision treatments and unparalleled safety.

"This is a major accomplishment in establishing ThermiRF as a safe and effective device for the treatment of nerves and soft tissue, using thermistor-regulated delivery of energy for aesthetic applications," said Paul Herchman, CEO of ThermiAesthetics. "Our unique technology has provided surgeons with access to an important and versatile platform technology which includes both micro-surgical and non-invasive tools. We are excited to continue our penetration into the U.S. market, and begin expansion of the ThermiRF solution to physicians worldwide."

Since its pre-commercial introduction in the United States in 2012 general plastic and facial plastic surgeons, dermatologists and cosmetic surgeons from the United States and Canada have used ThermiRF in a variety of clinical areas. ThermiRF applications are targeted towards patients seeking an “in-between” solution for various aesthetic complaints. There is growing demand by baby boomers, who are seeking advanced solutions, which fall “in-between” non-invasive treatments and major surgery. Brian M. Kinney, MD, a board-certified plastic surgeon, said, “Today’s aging baby boomers are asking for minimally invasive alternatives to traditional cosmetic surgery, but understand the limitations of topical, non-invasive approaches. ThermiRF allows me to provide safe and effective in-between solutions for patients who are asking for longer lasting treatments for frown lines, wrinkles of the face or neck, or who desire to avoid or delay getting a facelift. Now I have a tool which allows me to readily address these needs.”

Dr. Kinney is also serves as chairman of the ThermiAesthetics Clinical Advisory Council, an independent body consisting of more than 125 physicians , who actively collaborate, via hosted demonstrations and frequent live video conferences to advance the science of thermistor-regulated energy delivery, and refine treatment protocols for a myriad of cosmetic applications.

A number of studies are planned and underway which will further demonstrate the safety and effectiveness of ThermiRF for a number of cosmetic conditions, such as skin laxity of the face and body, axillary hyperhidrosis, cellulite, snoring and post-child bearing vaginal laxity. The company plans to continue to expand the size and role of the Clinical Advisory Council over the next year.

About ThermiAesthetics:

The ThermiAesthetics flagship product is the ThermiRF Temperature Controlled Radio Frequency Generator System and is FDA cleared for dermatological and general surgical procedures for electrocoagulation and hemostasis; and to create lesions in nervous tissue. ThermiRF is an advanced technology using finely controlled thermal energy. It is a multiuse platform, which promotes increased patient safety, and clinical effectiveness, while providing versatile solutions for physicians serving the aesthetic market.

ThermiRF features a unique temperature control feature, and uses proprietary hand pieces, which are designed for specific medical applications. These include a variety of disposable RF electrodes and cannulas, and reusable non-invasive hand pieces.

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