

Alma Lasers(TM) Receives FDA Clearance for the Accent(TM) Dual Mode RF System

BUFFALO GROVE, Ill. – Apr. 30 (SEND2PRESS NEWSWIRE) – Alma Lasers a global leader in laser, light-based, and radio frequency (RF) technologies used in aesthetic medicine announced today that it has received clearance from the U.S. Food and Drug Administration (FDA) to market the Accent(TM) Dual Mode RF System in the United States.



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Receiving its first FDA indication for the treatment of wrinkles and rhytids, the Accent System has been used successfully by medical professionals worldwide to treat a variety of dermatological and aesthetic conditions.

“We’re delighted to receive the marketing clearance for the Accent product in the U.S.,” stated Howard Kelly, CEO for Alma Lasers. “The unique dual mode RF modalities of the Accent system will provide physicians with the most advanced technology available in non-invasive aesthetic medicine, creating a higher standard in patient satisfaction. The Company is committed to pursuing additional clearances from the FDA, in order to expand the clinical indications for the Accent system in the United States.”

Non-invasive, non-ablative, and virtually pain free, the Accent system combines two radio frequency modes into one device. Each mode is delivered by

a discrete handpiece to enable volumetric RF thermotherapy at different tissue depths within the body.

In the BiPolar mode, RF energy penetrates the skin superficially, facilitating the treatment of areas where skin is thinner and more delicate such as areas of the face where the skin rests directly over the bone. The Alma proprietary UniPolar mode, delivers RF energy deep into the dermal and sub-dermal layers to efficiently treat large volumes of tissue. Unlike other RF based technologies, the Accent system does not require consumables. Therefore, treatments are clean, efficient and economical.

Ziv Karni PhD President and founder of Alma Lasers stated; "The Accent product was engineered for safety and ease of use while maximizing efficacy. The continuous movement of either handpiece results in a gradual build-up of heat to achieve the optimal therapeutic effect, while offering greater patient comfort. With over one thousand Accent systems installed world wide, the product has enjoyed an unparalleled safety record."

"Non-invasive treatments are the largest and fastest growing category in aesthetic medicine," said Yariv Matzliach, Executive Vice President of Global Marketing for Alma Lasers. "The Accent system has been approved for use in Europe, Asia, Australia, Latin America and Canada, where dermatologists, plastic surgeons, OB/GYN's and general practitioners have achieved outstanding results and a consistently high level of patient satisfaction. Now with its first FDA cleared indications, the Accent system is poised to provide medical professionals and their patients in the United States with a new level of safety, efficacy and satisfaction in the non-invasive treatment of wrinkles and rhytids using a combined treatment with Unipolar and Bipolar RF technologies."

According to one Principal Investigator in the FDA study, Macrene Alexiades-Armenakas, MD, PHD, Assistant Clinical Professor, Yale University School of Medicine, and Director, Dermatology and Laser Surgery in New York City, "I found the Accent system to be superior to prior generations of RF technology in the treatment of skin laxity, particularly on the neck. It is also a remarkable breakthrough that the system is painless and requires no anesthesia. Accent treatments can be performed rapidly with no downtime and can be applied concurrently with other non-ablative modalities, such as injectables to achieve better results in what is termed the 'non-surgical facelift.' Immediate skin tightening is evident and the results are often considered striking."

"We have found the Accent system to be very safe and relatively comfortable with a high percentage of responders," states David H. McDaniel, MD, Assistant Professor of Clinical Dermatology and Plastic Surgery, Eastern Virginia Medical School, and Director of the Institute of Anti-Aging Research Center of Virginia in Virginia Beach. "Compared to other RF devices we have used, treatment with the Accent system is much less painful, faster and easier to perform. It also allows more 'artistic' use on the face. Although responses vary, a high percentage of treated subjects showed a visible response. Some observe an immediate skin tightening of the face. Many of the

subjects noticed a difference in the way their clothes fit after a few treatment sessions. It can also be used as part of a broader spectrum of non-surgical facial rejuvenation treatments or procedures which might include fractional resurfacing, IPL or LED photomodulation, and Botox? or other injectable fillers.”

Maurice Sherman, MD, Associate Professor of Clinical Surgery, University of California – San Diego, and the owner of the Del Mar Cosmetic Medical Center in southern California, said “We obtained remarkably good results with the Accent system. It was consistent for all of the patients that followed the protocol. All of them showed an improvement. Some dramatic, some moderate, but every patient expressed satisfaction with the results. Everyone said that their skin felt tighter the day after the first treatment.” Added Dr. Sherman, “Of all the RF systems on the market today, I feel the Accent is the most effective technology out there.”

About Alma Lasers

With over 1000 Accent installations worldwide, Alma Lasers is a global developer, manufacturer and marketer of laser, light-based, and radio frequency devices for aesthetic applications. Since 1980, the founders of Alma Lasers have been at the forefront of innovative technologies for use in aesthetic medicine. Technical expertise combined with a thorough understanding of practitioners’ needs led to the development of Alma Lasers’ multi-technology / multi-application systems.

The Company’s mission is to provide modular, cost-effective and high performance systems that enable medical practitioners to confidently offer safe, effective, and profitable aesthetic treatments.

More information about Alma Lasers can be found at www.almalasers.com.

News issued by: Alma Lasers

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Original Story ID: (2786) :: 2007-04-0430-003

Original Keywords: Alma Lasers, laser, light-based, and radio frequency devices for aesthetic applications, technologies for use in aesthetic medicine, BiPolar mode, RF energy penetrates the skin superficially, Howard Kelly, Accent system, Accent Dual Mode RF, FDA approval Alma Lasers