



500 Apgar Drive
Somerset, NJ 08873
USA

Te☎: (1*) 732-563-0600
Fax: (1*) 732-563-1571
Web: www.lightage.com

Light Age Inc. receives FDA approval for the treatment of onychomycosis using its Q-Clear™ q-switched Nd:YAG laser system

Clearance by the Food and Drug Administration provides a new, effective way of treating infected nails using laser therapy.

September 28, 2011 – Light Age Inc., a Somerset, NJ based private developer and manufacturer of laser products, has received US FDA marketing approval for its Q-Clear™ laser systems for the treatment of onychomycosis. Onychomycosis, more commonly known as nail fungal infection, is caused by common dermatophytes, such as *Trichophyton rubrum*, that infect the nail bed and matrix. Because the infection resides in areas that are hard to access, such as the underside of the nail plate, it has been historically difficult to treat. Onychomycosis affects tens of millions of people in the United States and many more worldwide. In addition to causing disfigurement and discomfort, the resulting lesions provide access for other opportunistic diseases that can result in severe medical problems, especially for people with circulatory issues in their extremities, including diabetics, paraplegics, and the elderly. The Q-Clear™ laser system provides a revolutionary, minimally invasive and highly effective treatment for onychomycosis. With it, fast, effective, low cost treatments can now become commonly available through dermatologists, podiatrists, and other professional healthcare providers.

“Onychomycosis has long caused both physical harm and emotional distress to millions of people. Its treatment has been challenging: topical therapies have had limited efficacy and systemic medications have had significant and potentially serious side effects. As a result, treatment options have been limited and courses of treatment long, expensive, and frustrating,” commented Dr. Donald Heller, CEO of Light Age Inc. “Lasers provide a unique capability in penetrating the nail plate and dermal tissues and directly treating the infection, without causing significant side effects or pain.”

Dr. James Holfinger, of Southwest Foot and Ankle Associates, Inc. in Cleveland, Ohio, primary investigator for the 12 month randomized clinical study, added, “lasers now provide a superior option for treatment of onychomycosis. The Q-Clear laser system provides highly effective treatment for many patients without the need for use of systemic medications which often require blood testing to monitor for potentially serious complications”. Since pioneering the use of the Q-Clear™ laser system in the field of podiatry, Dr. Holfinger states “the unique characteristics of this laser provide advantages not associated with any other treatment or laser system currently available.”

The Q-Clear™ is the only q-switched laser system that has received FDA approval specifically for the clearance of nails infected by onychomycosis.

Ms. Betsy Reddington, Director of Regulatory Affairs at Light Age Inc. mentioned, “The Q-Clear™ has had FDA approval for general surgery and dermatology since 2003 and has been shown to be safe and effective in treating multiple indications for use in surgery, dermatology, and now in podiatry. In our 12-month randomized clinical study following subjects of both genders, including Caucasian, Asian, African

American, and Latino subjects, the Q-Clear™ laser system has proven to be substantially effective in clearance of dystrophic nails having a clinically apparent diagnosis of onychomycosis. Statistical analysis of results indicates significant apparent clearing in 97% of the subjects treated with an average clearance of affected areas of 56±7% at 98% level of confidence. The protocol employed was extremely well tolerated by patients; no pain was reported, although some patients reported feeling a low-level sensation on some involved nails. Reported patient satisfaction was 100%. No significant adverse reactions or responses were observed or reported. We are very proud to receive FDA approval specifically for the treatment of onychomycosis. We are even more happy to know our laser has been found to be safe and effective in treating a disease that affects so many people and which can be most troubling for individuals with compromised circulation in their extremities.”

About Light Age, Inc.

Since its founding in 1986, Light Age, Inc. has been the inventor, innovator, and preeminent developer of alexandrite laser technology as well as a pioneer in the development of many other advanced laser technologies. Additionally, Light Age has played a major role in creating and establishing numerous advanced applications based on solid-state laser media and nonlinear optical processes. Today, Light Age is a leading supplier of advanced laser systems worldwide for almost every application from fundamental research to medical diagnostics and therapeutics to aesthetic laser procedures. Its products are sold under its own name brands and in OEM and embedded products distributed by other device manufacturers. In addition to its commercial manufacturing, Light Age develops custom laser systems and new laser capabilities under contract and in strategic partnerships. Light Age frequently develops and engineers laser systems with flexible and/or highly specialized capabilities for applications requiring new, difficult, and sometimes seemingly impossible laser characteristics.

Pre viac informácií prosím kontaktujte lokálne zastúpenie firmy Light Age, Inc. – BETA plus spol. s r.o. na tel. čísle +421 57 4422422 alebo emailom na betaplus@betaplus.sk