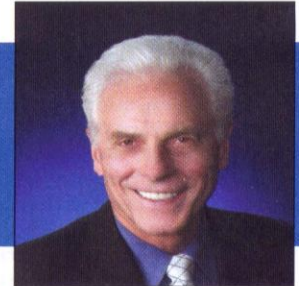




## Laser Therapy

### Introducing Low Level Laser Therapy to Pain Management

Low level laser therapy (LLLT) can be a safe and effective alternative to drugs in a variety of pain conditions.



By Larry Lytle, DDS, PhD

It is now understood that chronic pain can cause serious mental, social, employment, family, and marital problems, while increasing stress and shortening life.

Sun light and other sources of light have been used throughout the ages to treat various disorders, including pain, until the discovery of sulfa in 1932 by German chemist Gerhard Domagk.<sup>1</sup> "The sulfa discovery started the drug revolution and, for the past seven decades, drugs have been the treatment of choice. Most Americans are still waiting for the next "magic drug," "the magic bullet," "the cure all drug." Yet, despite acknowledged drug side effects, little attention has been given to alternative modalities, including low level laser therapy.<sup>2</sup> In fact, the Norwegian Health Technology Report states that low level laser therapy was twice as effective as NSAIDs for treating osteoarthritis pain.<sup>3</sup>

#### The FDA and Laser Technology

The question is often asked; is this low level laser approved by the Food and Drug Administration (FDA) which began regulating medical devices including low level lasers in the late 1980s. Technically, the FDA does not approve lasers.

The first step for any company that wants to sell lasers is to register the instrument for safety. The FDA determines safety by the potential for risk to the human eye at 20 centimeters. An important feature in classifying lasers depends on whether the laser is culminated – that is the beam comes to a point, or if the beam is linear and dissipates as the laser is moved further away. Following is a simplified explanation of the five laser classifications:<sup>4</sup>

**Class 1** is a laser that will not cause harm regardless of length of exposure and is considered a non-significant risk device. An example of this is the laser in bar code check out systems.

**Class 2** is a low power visible light laser (<1mW) that may cause damage to a person's eyes if exposed for a long enough pe-

riod of time. Examples are some laser pointers and range finding equipment.

**Class 3a** is continuous wave laser (1-5 mW) that can cause harm to the eyes if exposed for a long enough period of time. Examples are laser pointers and laser scanners. This class of laser should never be aimed at the eyes.

**Class 3b** is an intermediate powered laser (5-500 mW or pulsed 10 J/cm<sup>2</sup>). Uses are spectrometry and entertainment light shows. Direct viewing, or even diffuse reflections of the beam, will cause harm to the human eye and protective eyewear should be worn.

**Class 4** are high powered cutting lasers (>500mW or pulsed >10J/cm<sup>2</sup>). The direct beam and diffuse reflections are harmful to eyes and skin. Protective measures should be employed. Lasik eye surgical lasers are an example of this type of laser.

There are many low level laser instruments registered with the FDA and have been assigned accession numbers. Once registered, the instrument can be used for human use under the direction of an Investigational Review Board (IRB), or used as a veterinary laser.<sup>4</sup>

The second step is to complete clinical trials under the direction of an IRB and apply to the FDA for pre-market clearance. Once pre-market clearance is granted, then the company may make claims that their laser can be used to treat the condition that was studied in the clinical trials. Many doctors erroneously assume that once the company gets pre-market clearance that the laser is "approved" and can be used for anything. This is not true. Some companies take the liberty of advertising their lasers beyond what they were cleared for, but untruthful advertising is regulated by the Federal Trade Commission (FTC) not the FDA.<sup>5</sup>

Another way to get the FDA's blessing to sell lasers is by applying for 510k clearance. This application requires less time and does not require clinical trials. A company submits an application with the claim that their laser has some of the exact

same features as a previously-cleared device. While the 510k approach is much quicker, it has led to several lawsuits for patent violations. Some lasers, cleared under the 510k using another laser company's clinical trial, are no longer available due to the legal ramifications. According to Regulatory Insight, a Colorado based company that assists manufacturers in getting FDA clearance, there are currently over 35 different low level laser instruments cleared by the FDA, either by clinical trials or 510k applications. Many of the 510k clearances are based upon older heat producing laser instruments on which the patents have expired. These companies often make claims that their laser treats anything that heat would treat.

In the next issue, I will discuss how a low level laser works in pain management. ■

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