

Don't Get Burned!

The facts about Class IV lasers

We understand the confusion surrounding your decision to invest in LLLT. In order to investigate your own risks vs benefit assessment, and to honor our creed of Do no harm, there are certain facts about Class 4 lasers that need to be brought to your attention. (We invite you to investigate these facts, and inquire with any companies you may be researching)

fact

There has never been a Class IV laser proven by a Level (1) trial to demonstrate efficacy. All Class IV lasers failed to conduct the proper studies to prove their device; instead they took the path of least resistance and filed what is called a Substantial Equivalent. To get market clearance this way all one has to do is state the product shares the same characteristics and is intended for the same use as the predicate device. NO RESEARCH IS REQUIRED. Below is the actual intended use from the FDA and the predicate devices they used to garner clearance to market their products.

fact

Class IV laser companies make many claims about deeper penetration and continue to ignore the well proven systemic affects of low level lasers. We must also consider what their product is actually approved for and can easily surmise that this proves the exact opposite of what they claim— That they were cleared from the FDA as a topical heating device.

Lets follow the trail they took to gain approval....K Laser filed of 3 other devices (2) of which were Class 3 B lasers and (1) was Alt another Class IV laser. Companion filed of K Laser so they did not have to prove anything. Alt was the first Class IV laser to receive clearance, so the question begs how did they file? They filed of of a device called Bio Pack, and Bio Pack filed of a predicate device that was in commerce prior to 1976 which kept all of them from ever having to go through the process of a controlled study to prove their device was even effective... the sad truth is the original device they all relate back to is a heating lamp form the 70's.



Is this the kind of technology you want to offer your patients?... the equivalent to a device that dates backs to the 1970's?

The INTENDED USE/INDICATIONS FOR USE:

- ⊗ Infrared therapy to provide topical heating for temporary increase in local blood circulation
- ⊗ Temporary relief of minor muscles and joint aches, pains and stiffness
- ⊗ Relaxation of muscles
- ⊗ Muscles spasms
- ⊗ Minor pain and stiffness associated with arthritis

SUBSTANTIAL EQUIVALENCE (SE) RATIONALE:

K-Laser generates infrared therapy for treatment of selected medical conditions and shares the same or similar basic characteristics and the same intended use as the predicate device.

Predicate devices:

- ♥ ALT Laser, Model VTR 75
Cleared under K031613
- ♥ Vectra Genisys Laser System
Cleared under K 040662
- ♥ Solaris D890
Cleared under K040729

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Predicate Devices used to gain FDA market clearance:

- ♥ K-Laser Therapy Probe- Cleared under K050070 market clearance
- ♥ ALT Laser, Model VTR 75-- Cleared under K031612 market



Warning: Class IV Lasers May Cause Serious Burns: Do Not Use Over Sensitive Skin Areas or in the Presence of Poor Circulation

- ⊗ DO NOT allow any reflective object to fall into or obstruct the path of the laser energy produced by this device. Scattered or reflected laser energy can cause serious damage to eyes. The operator, all assistants, and the patient must remove all reflective objects (such as rings, metal watchbands, and jewelry) prior to treatment with this device. Indirect or direct eye contact with the output beam or at scattered laser light from any reflective surfaces from the laser will cause serious damage, irreparable corneal and/or retinal damage, and possible blindness to one or both eyes.
- ⊗ DO NOT use the System Controls or performance of procedures other than those specified in this manual may result in hazardous radiation exposure.
- ⊗ AVOID THE USE of flammable solvents. Anesthetics, oxidizing gases such as nitrous oxide (N₂O) and oxygen or endogenous gases. The high temperatures produced in normal use of this laser equipment may ignite some material, for example cotton or wool, when saturated with oxygen. The solvent of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used.
- ⊗ FAILURE TO COMPLY with all safety instructions and warnings may expose all participants to harmful levels of laser radiation and/or dangerous levels of electrical current.

Source: owners manuals.