

INDICATIONS FOR USE – Q-Clear™ Laser

The Light Age, Inc. Q-Clear™ Laser is a Q-Switched Nd:YAG Laser. Pulsed energy is emitted at 1064 nanometers in the near-infrared portion of the spectrum. With the optional frequency doubler installed, a 532 nm beam is emitted. The 532 nm emission is visible green light. Energy from the laser is delivered directly to the target area via the handpiece, which produces a circular beam on the skin. A red aiming beam is provided to allow the operator to precisely target the treatment area. The Q-clear™ Laser is equipped with safety features in conformance with 21 CFR Part 1040.

Intended Use:

The Light Age Q-Clear™ Laser is intended for the following uses:

1. For incision, excision, ablation, and vaporization of soft tissue for General Dermatology
2. The 1064 nm wavelength is indicated for:
 - Dark ink tattoo removal
 - Treatment of pigmented lesions (particularly Nevus of Ota)
 - Removal or lightening of hair
 - Skin resurfacing with or without adjuvant preparation
 - Treatment of common nevi
3. The 532 nm wavelength is indicated for
 - Removal of light ink (red, tan, purple, and orange) tattoos
 - Treatment of common nevi
 - Treatment of café-au-lait spots
 - Treatment of seborrheic keratoses
 - Treatment of vascular lesions, including facial and leg veins, telangiectasias, angiomas, hemangiomas, port wine stains, and most pigmented lesions (e.g. lentiginosities, and ephelides)

Safety and Efficacy

The Light Age Q-clear™ Laser does not raise new questions of safety or efficacy.