

Nuvo-Lase 660 Laser System
American Laser Medical
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**Summary of Safety and
Effectiveness Information**

Regulatory Authority:

Safe Medical Devices Act of 1990, 21 CFR 807.92

Company Name/Contact:

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Name of Device:

Trade Name: Nuvo-Lase 660 Laser System

Common Name: Dermatology Laser

Classification:

Powered surgical laser instruments are assigned the unique device classification code 79GEX. The published physical description of this device is found in 21 CFR, § 878.4810 (a) (2). This device classification section specifically describes argon laser systems. The American Laser Medical device is a CW 532 nm frequency doubled Nd:YAG laser system. However, for the purposes of this submission, American Laser Medical maintains that there is no substantial difference in CW frequency doubled Nd:YAG and argon laser systems. Presently, these lasers are considered Class II medical devices.

Description of Device:

The Nuvo-Lase 660 Laser System submission covers all of the internal parts, subassemblies and components as well as the completed device. The Nuvo-Lase Model 660 is a continuous wave frequency-doubled Nd:YAG laser system with output at 532 nm.

Treatment beam output for the Nuvo-Lase 660 laser 3 Watts continuous wave at 532 nm. The aiming beam is provided by an adjustable intensity incoherent white light source. Exposure times for the Nuvo-Lase 660 Laser System (in seconds) are 0.02, 0.05, 0.1, 0.25, 0.5, 1.0, and continuous.

Laser activation occurs by footswitch. Overall weight of the system is 20 lbs. (9 kg). The Nuvo-Lase 660 Laser System has dimensions of 10 X 14 X 5 inches (25 X 36 X 13 cm).

The electrical power requirement is 115 VAC 15 amp single phase. The system is air-cooled by fans.

Accessories available for use with the Nuvo-Lase 660 Laser include a focusing handpiece with interchangeable guide tips and/or the Hexascan Mark II. The Nuvo-Lase 660 Laser System is not a computer controlled device.

Intended Use:

The Nuvo-Lase 660 Laser System is intended for use in the treatment of selected vascular and pigmented lesions of the skin. Laser light is used to photocoagulate tissue based on the absorption characteristic of the targeted chromophore within the tissue.

Indications for Use:

The Nuvo-Lase 660 Laser is intended for use in the treatment of selected pigmented and vascularized lesions of the skin. Representative indications for use are:

**Nuvo-Lase Model 660 Laser System
For vascular lesions: (Green - 532 nm)**

1. Capillary Hemangioma (port wine hemangioma)
2. Strawberry hemangioma
3. Telangiectasia
4. Rosacea

For pigmented lesions: (Green - 532 nm).

1. Freckles
2. Age Spots
3. Cafe-au-lait
4. Lentigo

Comparison of Device Characteristics:

For vascular lesions:

The Nuvo-Lase 660 Laser System is substantially equivalent to the Laserscope Aura and the Lihtan 532 already in commercial distribution. The materials, design, intended use, method of manufacture, warnings, cautions, precautions and treatment parameters are substantially the same.

For pigmented lesions:

The Nuvo-Lase 660 Laser System is substantially equivalent to the Laserscope Aura and the Lihtan 532, already in commercial distribution. The materials, design, intended use, method of manufacture, warnings, cautions, precautions and treatment parameters are substantially the same.