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Alcon

LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH, TX 76134
(817) 551-8388

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510(K) SUMMARY

Submitted by:

Martin A. Kaufman
Manager, Regulatory Affairs, Surgical Devices
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76132
(817) 551-8388 (Phone)
(817) 551-4630 (Fax)

Trade Name: Ophthalas® 532 Solid State Photocoagulator
Common Name: Solid state ophthalmic laser photocoagulator
Classification Name: Ophthalmic Laser (per 21 CFR 886.4390)

1. Predicate Device

The legally marketed device(s) to which we are claiming equivalence to are the Ophthalas® 532 Photocoagulator marketed by Alcon Laboratories, and blue-green Argon Ophthalmic Lasers cleared for the Trabeculoplasty indication.

2. Device Description

The Ophthalas 532 Solid State Photocoagulator, and/or equivalent devices, are a pulsed solid state frequency doubled Nd:YAG laser producing a characteristic 532 nanometer (nm) wavelength light as the therapeutic beam. A 633 nm helium-neon (HeNe) laser is used for the aiming beam source.

3. Intended Use of the Device

The Ophthalas 532 laser is intended to be used in all clinical applications for which an Argon laser would be used in ophthalmic surgery, including, but not limited to Retinal and Macular Photocoagulation; Transcleral Cyclophotocoagulation; Internal Sclerostomy; Iridotomy; and Trabeculoplasty.

4. Summary of the Technological Characteristics of the Device

The Ophthalas 532 is a Neodymium-doped Yttrium Aluminum Garnet type laser which has been designed for ophthalmic use. LASER is an acronym for "Light Amplified by Stimulated Emission of Radiation." This laser delivers a 532 nm green laser beam (frequency doubled), a 633 nm HeNe (Helium-Neon) aiming beam, and a 1064 nm infrared laser beam.

The laser beam may be defined as a visible (i.e.; green 532 nm) or invisible (i.e.; 1064 nm), coherent monochromatic light beam.

The doubling process of the 1064 wavelength results when the infrared beam goes through a special crystal. The crystal is an optical dielectric that exhibits a non-linear optical response. The 532nm wavelength is produced by harmonic generation of the 1064nm laser beam.

5. Summary of the Performance Data

The Ophthalas 532 Laser consistently and safely produces a thermal lesion equivalent to those produced by conventional Argon lasers.

6. Conclusions

The Ophthalas 532 Laser is substantially equivalent to Argon lasers for the treatment of all clinical applications for which an Argon laser would be used in ophthalmic surgery, including, but not limited to Retinal and Macular Photocoagulation; Transcleral Cyclophotocoagulation; Internal Sclerostomy; Iridotomy; and Trabeculoplasty.