

510(k) Summary of Safety and Effectiveness

*The following information is submitted in accordance with the requirements of
21 CFR 807.92 :*

Submitted by :



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Device Name :

Classification Name : Ophthalmic Laser

Common / Usual Name : Ophthalmic Laser Photocoagulator

Proprietary Name : VIRIDIS
Frequency Doubled Nd:YAG Photocoagulator

Other Proprietary Name : EVERGREEN 532
Frequency Doubled Nd:YAG Photocoagulator

Classification :

Devices Classification Panel : Ophthalmic

Product code : 86HQF

Ophthalmic lasers are Class II medical devices in accordance with 21 CFR § 886.4390.

Note : "VIRIDIS" and "EVERGREEN 532" are identical.

Only the housing is different.

510(k) Summary of Safety and Effectiveness

Predicate Devices :

- An other Frequency Doubled Nd:YAG Photocoagulator :
The EMERALD from Crystal Focus
- A Continuous-wave Argon Laser.:
The NOVUS 2000 from Coherent

Device Description

The **laser source** is an Nd:YAG Slab, pumped by a Laser Diode (810 nm), with a frequency doubling crystal (KTP).

The treatment beam is delivered through a delivery system and is aimed using a Red Laser Diode (670 nm).

The 3 possible delivery systems are the following :

- Slit lamp adaptor
- Indirect ophthalmoscope adaptor
- Endocular probe adaptor

Output power of all these delivery systems have a maximum of 1.5 Watts.

Intended Use :

Used with a slit lamp adaptor, this system is **indicated for use** in retinal photocoagulation for the treatment of ophthalmic conditions including : Proliferative Diabetic Retinopathy, Macular Degeneration, and Retinal Detachment.

Predicate Comparison :

A chart comparing the VIRIDIS (or EVERGREEN 532) with the 2 predicate devices, demonstrating substantial equivalence, is attached.

510(k) Summary of Safety and Effectiveness

Device Comparison

Manufacturer	Coherent Medical	B.V.International	Crystal Focus
Model	NOVUS 2000	VIRIDIS or EVERGREEN 532	EMERALD
Same Intended Use	Retinal Photocoagulation for the treatment of Ophthalmic conditions.		
Same type of Delivery systems	1°) Slit Lamp adaptor with Zoom 2°) Indirect Ophthalmoscope adaptor 3°) Endocular Probe		
Lasing medium	Argon	ND:YAG	ND:YAG
Pumping system	High Voltage	Diode Laser 810 nm	Flash
Doubling Frequency Crystal	---	KTP	KTP
Output Wavelength	488 - 514 nm	532 nm	532 nm
Pulsing system	Continuous	Pseudo-Continuous	Pulsed
Pulse Duration	----	25 micro sec.	1 micro sec.
Average Power	2.5 W	1.5 W	2 W
Pulse Repetition Rate	Continuous	12 000 Hz	10 000 Hz
Mini. Focal Spot Size : Diameter	50 micro meters	50 micro meters	50 micro meters
Aiming beam :	Coaxial with treatment beam		
Aiming beam : type	He-Ne laser	Diode Laser	He-Ne laser
Aiming beam : Wavelength	632 nm	670 nm	632 nm
Cooling method	Internally liquid cooled	Solid state cooling	Internally liquid cooled
Exposure Selections (t)	0.01s to continuous	0.01 -0.02 -0.05 -0.07 - 0.1 -0.2 -0.3 -0.4 -0.5 -0.7 -1.0 -2.0 -3.0 sec.	0.01- 0.02- 0.05- 0.1- 0.2- 0.3- 0.4 -0.5 -0.7 -1.0 and 3.0 sec.
Power requirements : Voltage	208 - 240 Vac	100 to 240 Vac	208 - 240 Vac
Power requirements : Current	45 A	5 A	13 A