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K111460

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

1. Submitter Information

Submitter: Opto Eletrônica S/A

Address: NO. 1071 - Joaquim Augusto Ribeiro de Souza street– Jardim Santa Felícia - São Carlos – SP/ Brazil

Phone: + 55 (16) 2106-7029

Contact name: Paulo Aneas Lichti

Date Prepared: march 10, 2011

Registration number: 9613205

2. U.S. Agent to respond to FDA requests:

Establishment: Opto Usa Corporation

Contact Person: Paulo Aneas Lichti

Address: 12550 BISCAYNE BLVD, 605, MIAMI - FL – 33181

Phone: 1 305 981 2979 – **Fax:** 1 305 981 2980

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3. Device Classification Name

Device Name: Opto Hyalus Green Laser

Common name: Ophthalmic Laser, Surgical Laser

Classification name:

HQF, Laser, Ophthalmic

Regulation Number:

21 CFR 886.4390, Ophthalmic Laser

Regulatory Class: II

Performance standards: 21 CFR 1040.10

4. Predicate Device Name:

IRIS Medical OcuLight GL/GLx Laser Systems, Iridex Corporation, K031665

5. Product Description

The Opto Hyalus Green Laser solid state, frequency-doubled, green Nd;YAG surgical laser system is an instrument used in the photothermolysis (photocoagulation) of soft tissue at en emission wavelength of 532nm.

The equipment consists of three encoders which enable the physician to adjust the pulse duration, the laser power and the interval between successive pulses. All information is displayed on a color display 240x324 pixels TFT technology. On this display there is a touch-screen film responsible for the navigation software and by setting preferences, such as loudness, intensity laser sighting and display brightness.

Physicians have the option of applying single pulses or pulse trains previously adjusted. Power levels ranging from 50mW up to 2000mW, with resolution of 10mW. The duration can be set between 10ms and 1000 ms with a resolution of 10ms. The interval between pulses can be set between 50ms and 3000ms with 10ms resolution or can be set to single pulse (in this case, the range is set to zero).

6. Intended Use

The Opto Hyalus Green Laser is indicated for retinal photocoagulation. Used for the following ophthalmic medical condition and treatment:

- Retinal photocoagulation, panretinal photocoagulation and intravitreal endophotocoagulation of vascular and structural abnormalities of the retina and choroids, including:
    - ✓ Proliferative and nonproliferative diabetic retinopathy
    - ✓ Choroidal neovascularization
    - ✓ Branch retinal vein occlusion
    - ✓ The treatment of choroidal neovascularization associated with wet age related macular degeneration Retinal tears and detachments
- Iridotomy, iridectomy, and trabeculoplasty in angle closure glaucoma and open angle glaucoma

Advantages of the LIO (Laser Indirect Ophthalmoscope)

1. Allow binocular visualization of the peripheral retina;
2. Used to evaluate patients who must be examined in a supine position;
3. The region of the vitreous band can be inspected and treated;
4. Allow easier treatment of superior quadrant than does the endolaser;
5. Allow better visibility through the phakic gas-filled eyes since there are fewer reflections than present with biconcave lenses;
6. Minimizes the risk of lens damage by the endolaser when treating the far periphery;
7. The peripheral edges of a giant tear can be completely inspected and treated with the Laser Indirect Ophthalmoscope;
8. Avoids discomfort induced by pressure from a contact lens in the postoperative patient;
9. Reduces the stress to recently sutured wounds;
10. Minimizes the risk of infection.

7. Technical Characteristics

The Opto Hyalus Green Laser beam has a wavelength of 532nm, which is in the visible spectrum and is a green light. A red aiming beam is used to position the treatment green beam prior to delivery.

The Opto Hyalus Green Laser is a solid state, Optical Pumped Semiconductor surgical laser.

It's an instrument used in the photothermolysis (photocoagulation) of soft tissue at en emission wavelength of 532nm.

Compatible delivery devices include: slit lamp adapters/, laser indirect ophthalmoscopes (LIO) and Probe. All these accessories are specific for Opto Hyalus Green Laser.

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8. Accessories

- Eye Safety Filter
- Pedal Multifunctional
- Slit Lamp Adapter

9. Compatible Delivery Devices

- Ophthalmoscope
- Probe

10. Performance Standard

Opto Hyalus Green Laser is designed, tested and wilt be manufactured in accordance with both mandatory and voluntary standards, including:

- IEC 60825-1:2007, Safety of laser products - Part I : Equipment classification, requirements and user's guide.
- IEC 60601-2-22: Ed 1995, Medical electrical Equipment - Part 2 : Particular requirements for the safety of diagnostic and therapeutic laser equipment.
- IEC 60601-1: 1988 + AI: 1991 + A2:1995, Medical Electrical equipment -Part I : general requirement for safety.
- IEC 60601-1-2: 200 1, Medical Electrical equipment -Part I : General requirements for safety-2, Collateral Standard : electromagnetic compatibility - requirements and tests.
- IEC 6060 1-1-4: 2000, Medical electrical equipment - Part I : General requirements for safety -4 - Collateral standard : Programmable electrical medical systems, edition 1.1.
- The device also complies with European Medical Directive 93/42/EEC ± Amendment 2007/47/EEC and the US Federal Performance Standards 21 CFR 1002. 10 Requirements (21 CFR 1040. 10 and 21 CFR 1040.11 for Class IV Laser). Part 1010.2 and 1010.3,Part 820 - Quality System Regulation, and have passed ISO 9001 and 13485 System Certification.
- IEC 62304:2006, medical device software - Software life cycle processes

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11. Discussion of similarities and Differences with the Predicate Product

Opto Hyalus Green Laser share the same indications for use and safety compliance, similar design features, functional features, and therefore are substantially equivalent to the predicate device , the IRIS Medical OcuLight GL Laser Systems (K031665). In addition a review of the predicate device demonstrate that the Opto Hyalus Green Laser is safe and effective as the predicate device as they share equivalent specifications / characteristics and are used to perform the same indicated surgical procedures.
There is no relevant difference in the specifications/characteristics of the Opto Hyalus Green Laser and its predicate IRIS Medical OcuLight GL Laser Systems (K031665).

Conclusion:
Opto Hyalus Green Laser use the same fundamental technology features as the IRIS Medical OcuLight GL Laser Systems (K031665) and delivers the same level of effectiveness. Therefore, it is concluded that there is no significant difference in the basic function, safety and effectiveness between the IRIS Medical OcuLight GL Laser Systems (Predicate Device) and the Opto Hyalus Green Laser.
The Opto Hyalus Green Laser is substantially equivalent to predicate devices currently legally marketed for treatments in ophthalmology.

12. Non-clinical performance data and conclusions from non-clinical tests

Laboratory testing was conducted to validate and verify that the proposed device, Opto Hyalus Green Laser met all design specifications and was substantially equivalent to the predicate device.

Clinical Conclusion: No Clinical information is required.

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13. Conclusion

Based on the information in this notification we concluded that Opto Hyalus Green Laser is substantially equivalent to predicate device currently legally marketed for the indication of retinal photocoagulation laser. Only applicable to uses in ophthalmology.

The Opto Hyalus Green Laser shares the same intended use, indications for use, and similar technical characteristics to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 20 2012

Opto Electronic S/A
% Mr. Paulo Aneas Lichti
Joaquim A.R. De Souza Street
1071-Jardim Santa Felicia
Sao Carlos, Sao Paulo Brazil 13630-330

Re: K111460
Trade/Device Name: Opto Hyalus Green Laser
Regulation Number: 21 CFR 886.4390
Regulation Name: Opthalmic laser
Regulatory Class: Class II
Product Code: HQF
Dated: August 09, 2012
Received: August 17, 2012

Dear Mr. Lichti:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if know): K111460

Device Name: Opto Hyalus Green Laser

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  - ✓ The treatment of choroidal neovascularization associated with wet age related macular degeneration Retinal tears and detachments
- Iridotomy, iridectomy, and trabeculoplasty in angle closure glaucoma and open angle glaucoma

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) Number K111460

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