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Executive Summary

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

Prepared on: 03/23/2011

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

3. Device Classification Name

Device Name: Opto Mitra Yellow Laser

Common name: Ophthalmic Laser, Surgical Laser

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Classification name:

HQF, Laser, Ophthalmic

GEX, Powered Laser Surgical Instrument

Regulation Number:

21 CFR 886.4390, Ophthalmic Laser

21 CFR 878.4810, Surgical Devices

Regulatory Class:

Class II

Performance standards:

21 CFR 1040.10

4. Predicate Device Name:

Iridex IQ 577, Iridex Corporation, K071687

Nidek Multicolor Laser Photocoagulator System MC-500, k110228

5. Product Description

The Photocoagulator Opto Mitra Yellow Laser is equipment capable of making human retinal photocoagulation by laser application at 586nm (yellow laser). The coagulation (clotting) of tissue using a laser which produces light in the visible yellow (586nm) wavelength that is selectively absorbed by hemoglobin, the pigment in red blood cells, in order to seal off bleeding blood vessels. Photocoagulation has diverse uses such as, for example, in cancer treatment to destroy blood vessels entering a tumor and depriving it from nutrients; in the

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treatment of a detached retina, to destroy abnormal blood vessels in the retina, to treat tumors in the eye, etc.

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 100ms and 3000 ms with a resolution of 10ms. The interval between pulses can be set between 100ms and 3000ms with 10ms resolution or can be set to single pulse (in this case, the range is set to zero).

6. Indicated for Use

Indicated for use in photocoagulation of both anterior and posterior segments, including:

- 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
  - ✓ Retinopathy of prematurity

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- Iridotomy, iridectomy, and trabeculoplasty in angle closure glaucoma and open angle glaucoma

7. Intended Use

Intended for use in ophthalmic surgical procedures.

8. Target Population

Individuals of all ages with diabetic retinopathy, glaucoma, or who have suffered any trauma causing a retinal detachment. Premature child with symptoms of prematurity retinopathy.

9. Technical Characteristics

The Opto Mitra Yellow Laser beam has a wavelength of 586nm, which is in the visible spectrum and is a yellow light. A red aiming beam is used to position the treatment Yellow beam prior to delivery.

The Opto Mitra Yellow 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 586nm.

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

- **Laser specification:**
  - Laser of 586nm (± 3nm), with a maximum output of 2000mW, resolution of 10mW and maximum Error of ± 20% in relation to the power set;
  - Laser Aim of 635nm (± 20nm), with a maximum output of 0.7mW (± 0.2mW);

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- **Pulse Duration:**
  - From 10ms to 1000ms with a maximum Error of 10%.
- **Interval between Pulses:**
  - From 50ms to 3000ms with a maximum Error of 10%.
  - The single pulse can be used – This option enables activating a single pulse with a pre-selected duration.
- **Operating range in the FastPulse configuration:**
  - FastPulse Period: from 1800 µs to 2200 µs (± 100 µs);
  - Duty-Cycle of the FastPulse : from 5% to 15% (± 1%) of the period chosen (time "on");
- **Operational Characteristics:**
  - Autoprograming according to the type of accessory coupled to the Opto Mitra Yellow Laser, through the Autokey;
  - Aiming Beam and Power Laser Divergence: single optical path, with coupling of the beams set at 100% of the units produced;
  - Automatic mode selection according to the accessory used, through the AutoKey;
  - Accessories such as Endoprobes, Slit Lamp Adapter and Ophthalmoscopes are connected to the main unit through the "optical fiber" opening, which is an optical-mechanical connector;
  - Emergency Key;
  - TFT Color Display with 32000 colors;
  - Touchscreen – Activation of commands by simply touching the display;
  - Control buttons without final stroke and with back lighting.

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10. Accessories

- Eye Safety Filter
- Pedal Multifunctional
- Slit Lamp Adapter

11. Compatible Delivery Devices

- Ophthalmoscope
- Probe

12. Performance Standard

Opto Mitra Yellow Laser is designed, tested and will 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 has passed ISO 9001 and 13485 System Certification.
- IEC 62304:2006, medical device software - Software life cycle processes

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13. Discussion of similarities and Differences from the Predicate Product

Opto Mitra Yellow Laser shares the same indications for use and safety compliance, similar design features, functional features, and therefore are substantially equivalent to the predicate device , K071687 and k110228 . In addition, a review of the predicate device shows that the Opto Mitra Yellow 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.
The only difference in the specifications/characteristics of the Opto Mitra Yellow Laser and its predicate K071687 is as follows:

1. Opto Mitra Yellow Laser has a wavelength of 586nm and 577nm for IQ 577. This difference is not viewed as being clinically significant.

Conclusion:
Opto Mitra Yellow Laser uses the same fundamental technology features as the IQ 577 and delivers the same level of effectiveness. Therefore, the conclusion that there is no significant difference in the basic function, safety and effectiveness between the K071687 and k110228 (Predicate Device) and the Opto Mitra Yellow Laser.
The Opto Mitra Yellow Laser is substantially equivalent to predicate devices currently legally marketed for treatments in ophthalmology.

14. Non-clinical performance data and conclusions from non-clinical tests
Laboratory testing was conducted to validate and verify that the proposed device, Opto Mitra Yellow Laser meets all design specifications and is substantially equivalent to the predicate device.

15. Conclusion
Based on the information in this notification we conclude that Opto Mitra Yellow Laser is substantially equivalent to predicate devices currently legally marketed for the indication of retinal photocoagulation laser. Only applicable for use in ophthalmology.
The Opto Mitra Yellow 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

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Opto Eletronica S/A
% Mr. Paulo Aneas Lichti
Joaquim A.R. de Souza Street
1071 - Jardim Santa Felicia
Sao Carlos, San Paulo
Brazil 13563-330

Re: K111643
Trade/Device Name: Opto Mitra Yellow Laser
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: Class II
Product Code: HQF
Dated: October 21, 2011
Received: October 24, 2011

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 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical 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,

for 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): K111643

Device Name: Opto Mitra Yellow Laser

The Opto Mitra Yellow Laser is indicated for retinal photocoagulation. Used for the following ophthalmic medical condition end 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
  - ✓ Retinopathy of prematurity
- 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
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k)_____

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

510(k) Number K111643