OCT - 3 1997

510 (K) SUMMARY

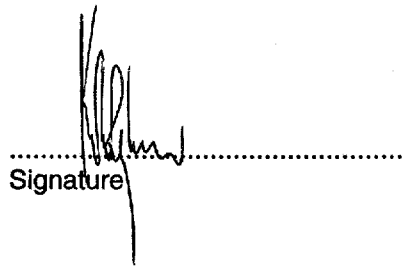
K972514

This is a 510(K) Summary in accordance with CFR 807.92.

1. SUBMITTERS NAME, ADDRESS:

Taracan Pty Ltd trading in the USA as
Laserex Systems
258 Halifax Street
Adelaide, South Australia 5000
AUSTRALIA

Corresponding Official:
Keith R. Degenhardt
Managing Director/CEO
Telephone: 61-8-82236644
Facsimile: 61-8-82326277



Signature

Date: 6/6/97

2. DEVICE NAME

Laserex Model LP1532.

3. PREDICATE DEVICE IDENTIFICATION

3.1 Name(s)

The predicate devices are:
1. Alcon Ophthalas 532.
2. Alcon EyeLite
3. Iris Occulite
4. Nidek Prima

3.2 Predicate Device Company

1. Alcon Surgical Inc
2. Alcon Surgical Inc
3. Iridex Corporation Inc
4. Nidek Medical Inc

4. INTENDED USES

4.1 The intended uses for this product are;

- Retinal Photocoagulation
- Pan Retinal Photocoagulation
- Endophotocoagulation.
- Photocoagulation for Macular Degeneration
- Laser Trabeculoplasty

4.2 A General Description of these Treatments are;

The intended uses for this product are:
Retinal treatments, including;

- Retinal Photocoagulation
- Pan Retinal Photocoagulation
- Endophotocoagulation

These treatments involve the destruction of neovascular complexes, to obliterate areas of microinfarction or capillary closure.
Retinal Photocoagulation will be carried out using principally the Slitlamp Delivery System accessory.
Pan Retinal Photocoagulation will be carried out using either of the Laser Indirect Ophthalmoscope or the Slitlamp Delivery System accessory.
Endophotocoagulation will be carried out using any one of the three variants of the endoprobe accessories, namely Straight, Curved or Aspirating Endooccular Probes.

Photocoagulation for Macular Degeneration involves the destruction of leaking vessels in the macular and paramacular region, and ultimately to produce a chorioretinal adhesion that will resist ongoing vitreoretinal traction. This treatment will be carried out using the slitlamp microscope mounted Slitlamp Delivery System accessory.

Laser Trabeculoplasty, the photocoagulation of the trabecular meshwork to create apertures and increase the flow of the aqueous humor in order to treat open-angle glaucoma. This treatment will be carried out using the slitlamp microscope mounted Slitlamp Delivery System accessory.

5. DEVICE DESCRIPTION

5.1 General

The LP1532 is a compact, solid state laser photocoagulator intended for ophthalmic use. It produces laser energy intended to be directed into the eye by a suitably qualified physician, via a range of laser delivery accessories namely;

- Laser Endoprobes
- Laser Indirect Ophthalmoscope
- Slitlamp Delivery Systems

The LP1532 is a frequency doubled Nd:YAG Laser operating in the visible green wavelength spectrum (532 nanometers).

5.2 Specifications

Size:

Width:	12" (310 mm)
Length:	20" (510 mm)
Height:	7.5" (190 mm)
Weight:	37 lbs (17 kg)

Power/Electrical Requirements:

Voltage:	110 or 220 VAC
Frequency:	50 or 60 Hz
Electrical power:	450 Watts
Insulation class:	Class 1 (UL 2601-1)

Laser Characteristics:

Treatment laser beam

Laser class:	Class IV (4)
Laser wavelength:	532 nm
Laser power:	30 mW min, 2 W max.

Aiming laser beam

Laser class:	Class II (2)
Laser wavelength:	635 nm
Laser power:	0.05 to 0.95 mW

5.3 Significant Changes/Modifications from Predicate Device

There are no significant changes or modifications from the predicate products that affect safety, effectiveness, or the intended use of the product.

5.4 Accessories

The following accessories are intended for use with the LP 1532 laser :

- Laser Endo Probes.
- Slitlamp Delivery System.
- Laser Indirect Ophthalmoscope.

Additional information is provided in the table below

	510 (K) DEVICE	PREDICATE DEVICE			
CHARACTERISTIC COMPARED	**LASEREX LP-1532**	**ALCON OPHTHALAS 532**	**IRIS**	**NIDEK**	**ALCON EyeLite**
Accessories					
Endo Probes	Straight, curved and aspirating	Straight, curved and aspirating	Straight and curved available	Endo Probes available	Straight, curved and aspirating
Laser Indirect Ophthalmo-scope	Adapted Heine	Adapted Keeler Fison	Adapted Heine	Nidek LIO	Adapted Keeler Fison
Slitlamp Adaptors	To fit • Zeiss • Haag Streit Combo for use with Laserex YAG	To fit • Zeiss • Haag Streit Combo for use with Laserex YAG	To fit • Zeiss • Haag Streit	To fit • Zeiss • Haag Streit Combo for use with NIDEK YAGs	To fit • Zeiss • Haag Streit
Spot Size	50-500 microns	50-1000 microns	75- 500 microns		
Operating Microscope Filters	• Zeiss OPMI-6 • Wild • Möeller				• Zeiss OPMI-6 • Wild • Möeller

6. DEVICE LABELS

Refer to Appendix A for all device labelling information including;

- Advertising brochure
- Description and directions for use
- Product labels (including accessories)

7. COMPARATIVE INFORMATION

The following table displays the similarities and differences of the new device to the legally marketed devices to which equivalency is claimed.

Characteristic Compared	510(k) DEVICE	PREDICATE DEVICES			
	LASEREX LP-1532	**ALCON OPHTHALAS 532**	**IRIS OCCULITE**	**NIDEK PRIMA**	**ALCON EyeLyte**
Laser Power (W)	Up to 2W	Up to 3W	Up to 1.2W	1.5W	Up to 1.7W
Laser Wavelength (nm)	532nm	532nm	532nm	532nm	532nm
Laser Class	IV	IV	IV	IV	IV
Exposure Time (sec)	0.01 to 2.0 sec	0.01 to 2.0 sec and CW	0.05 to 1.0 sec	0.02 to 3 sec	0.01 to 2.0 sec and CW
Aiming Laser Type	Red Diode	HeNe	Red Diode	Red Diode	Red Diode
Aiming Laser Power	0.05 to 0.95 mW continuously variable	4 intensities selectable up to 1 mw	0 to1mW	0.2 to 0.8mW	Continuously variable up to 1 mw
Aiming Wavelength	635nm	633nm	set between 630 - 650nm	633nm	670nm
Electrical Supply Voltage	100-120VAC 220-250VAC single phase 50/60 Hz	220 VAC single phase	90-240 VAC 50/60 Hz	100/120/ 230 VAC 50/60 Hz	100-120 VAC 8 A single phase 220-240 VAC 4 A single phase
Electrical Power Consumption	450W	3K W	300W	1500W	800 W
Weight	17Kg	99Kg	8.1Kg	32Kg	16Kg
Size	W 31cm D 51cm H 19cm	W 36cm D 81cm H 80cm	W.30cm D 15cm H 30cm	W 30cm D 42cm H 70cm	W 38.7cm D 44.6 cm H 21.8 cm
Environment					
Temperature	15 - 35 degrees C	15 - 30 degrees C	not specified	5 - 35 degrees C	15 - 35 degrees C
Humidity	Up to 85% RH	Up to 85% RH	not specified	5 - 95% RH non condensing	Up to 85% RH

Repeat Interval Duration **Cooling**	Selectable 0.1,0.2,0.3,0.40.5,0.6,0.7, 0.80.9,1.0 sec Air cooled	Selectable 0.2, 0.5, 0.7, 0.9 sec Internal water cooling system	Selectable Air cooled	0.2 to 1.0 sec in to 0.1 sec intervals Internal water cooling system	Selectable 0.1, 0.2, 0.3, 0.4, 0.5, 0.6, 0.8, 0.9,1.0 sec Air cooled
Scientific concepts that form the basis for the device	- Green laser source - Generated by means of a laser diode pumped, frequency doubled Yag laser. - Diode pumping configuration very efficient, permitting air cooling - Energy controlled by means of an operator by means of a software driven control system - Energy delivered to target tissue by a range of fiberoptic beam delivery systems	- Green laser source - Generated by means of an arclamp pumped, frequency doubled Yag laser. - Arclamp pumping configuration relatively inefficient, requiring closed loop water cooling - Energy controlled by means of an operator by means of a software driven control system - Energy delivered to target tissue by a range of fiberoptic beam delivery systems	- Green laser source - Generated by means of a laser diode pumped, frequency doubled Yag laser. - Diode pumping configuration very efficient, permitting air cooling - Energy controlled by means of an operator by means of a software driven control system - Energy delivered to target tissue by a range of fiberoptic beam delivery systems	- Green laser source - Generated by means of an arclamp pumped, frequency doubled Yag laser. - Arclamp pumping configuration relatively inefficient, requiring closed loop water cooling - Energy controlled by means of an operator by means of a software driven control system - Energy delivered to target tissue by a range of fiberoptic beam delivery systems	- Green laser source - Generated by means of a laser diode pumped, frequency doubled Yag laser. - Diode pumping configuration very efficient, permitting air cooling - Energy controlled by means of an operator by means of a software driven control system - Energy delivered to target tissue by a range of fiberoptic beam delivery systems
Intended Uses	Retinal photocoagulation Panretinal photocoagulation, Photocoagulation for Macular Degeneration Trabeculoplasty Endophotocoagulation	Panretinal photocoagulation, Photocoagulation for Macular Degeneration Subretinal neovascularization, Trabeculoplasty, Pneumatic retinopexy, Retinal tears, Retinal detachments, *Transscleral* cyclophotocoagulation, Endophotocoagulation	Retinal photocoagulation, Anterior segment procedures.	Retinal photocoagulation, Subretinal neovascularization, Closing of retinal arteriols.	Panretinal photocoagulation, Photocoagulation for Macular Degeneration Subretinal neovascularization, Trabeculoplasty Pneumatic retinopexy Retinal tears Retinal detachments *Endophotocoagulation*

8. BIOCOMPATIBILITY AND STERILIZATION INFORMATION

The laser endo probe accessories are the only components of the device that are patient contacting and supplied sterilized.

We are sourcing these probes from:

Creative Medical Products, Inc
5988 Mid Rivers Mail Drive
Suite 236
St Charles MO 63304

Owner/Operator Registration No. 9023612
Establishment Registration No. 1933418

They have provided the following information to us regarding the 510(K) approvals for these probes;

- FDA 510(K) approval number #K954307 applies to the straight and curved probes.

- FDA 510(K) approval number # K954308 applies to the aspirating laser probes.

These are the only probes we will be supplying with the device. Additional information provided by Creative Medical Products Inc is contained in Appendix B.

9. SOFTWARE VALIDATION & VERIFICATION

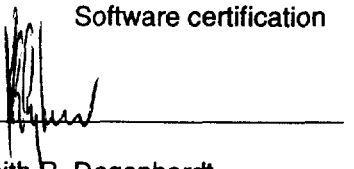
In accordance with the Reviewer Guidance for Computer Controlled Medical Devices a review of the level of concern for the LP-1532 has been identified to be Minor to Moderate. Operation of the LP-1532 directly affects the patient such that failures or latent design flaws may result in Minor to Moderate patient injury.

The software development process has not yet been completed but we believe that an equivalence determination can be made prior to completion. The following data is provided in Appendix C. *

- System and software requirements and design
- Software development
- Verification and validation

I certify that in my capacity as Managing Director/CEO of Taracan Pty Ltd, I will ensure that the described processes will be completed and the following will be completed;

- Test results and analysis
- Software certification

Signed: 

Name: Keith R. Degenhardt
Position: Managing Director
Date: 6/6/97

* Derived from 510(K) Memorandum # K91-1 Software Documentation Matrix.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 1997

Mr. Keith R. Degenhardt
Managing Director
Laserex Systems
258 Halifax Street
Adelaide, South Australia 5000
AUSTRALIA

Re: K972514
Trade Name: Laserex LP1532 Photocoagulator
Regulatory Class: II
Product Code: HQF
Dated: June 6, 1997
Received: July 7, 1997

Dear Mr. Degenhardt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K972514

Device Name: LASEREX LP1532 PHOTOCOAGULATOR

Indications For Use:

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The indication for use for this product are;

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- Photocoagulation for Macular Degeneration
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972514

Prescription Use √ OR Over-The-Counter Use _____
21 CFR 801.109)

(Optional Format 1-2-96)