

**Summary of Safety and Effectiveness Information**  
Safe Medical Devices Act of 1990, 21CFR807.92

Reliant Technologies, Inc.  
**Unica 315M R/G CO<sub>2</sub> Laser System**

**1. Device Name(s)**

**Trade Name:** Unica 315M R/G CO<sub>2</sub> Surgical Laser System

**Common Name:** CO<sub>2</sub> Surgical Laser

**Classification Name:** Instrument, Surgical, Powered, Laser

§ 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology. Classification: Class II.

**Classification Panel:** General & Plastic Surgery Devices Panel

**Product Code(s):** 79-GEX

**2. Establishment Name & Registration Number:**

**Name:** Reliant Technologies, Inc.

**Number:** 2950711

**3. Special Controls:**

This device complies with CDRH radiation control regulations as outlined in:  
21 CFR §1040, Performance Standards for Light Emitting Products  
21 CFR §1010, Performance Standards for Electronic Products, general.

**4. Labeling:**

The Unica 315M R/G is indicated for use as a surgical instrument to vaporize, incise, excise, ablate or photocoagulate soft tissue in general surgical procedures.

Required laser warning and caution statements are displayed as required for surgical laser devices.

## 5. Device Description:

<b>Weight:</b>	33 lb. (15 kg.)
<b>Dimensions:</b>	<b>Length:</b> 19.6 in. (49 cm.)
	<b>Height (folded arm):</b> 7.5 in. (18 cm.)
	<b>Width:</b> 6.4 in. (16 cm.)
<b>Main Laser Source:</b>	CO <sub>2</sub> laser, sealed wave guide tube TEM00.
<b>Treatment Beam Wavelength:</b>	10,600 nm CO <sub>2</sub> laser
<b>Aiming Beam Wavelength:</b>	532 nm KTP or 635 nm GaAlAs-laser - max. output 5 milliwatt.
<b>Modes of Operation*:</b>	Superpulse/Pulse/Continuous Single or Repeat pulse trains
<b>Beam Delivery:</b>	4 joint articulated arm that can be partially folded into the laser.
<b>Battery backup:</b>	Equipped with backup battery for 1 to 5 hours of operation depending on output power etc.
<b>Battery charge cycle:</b>	Full charge is achieved in 5 hours
<b>Cooling system:</b>	Internal cooling to instrument case. Overheat protection circuit.
<b>Electric requirements:</b>	Single phase 220-230V 50 Hz, <0.5A, or Single phase 110-120V 60 Hz, <1.0A.

\*Reliant Technologies, Inc. continually incorporates innovations into its products. Product specifications may change without notice.

- It contains a sealed laser tube, i.e. no gas filling is needed. The typical life time of the laser tube is more than 10,000 hours of operation.
- It is mechanically robust and electrically very safe - does not contain any higher voltage than 32 volts.
- It is easy to transport. The 315 M can be hand-carried without difficulty. The articulated arm can be partially folded into the laser.
- It has a backup battery. The laser output is independent of any line voltage fluctuations or even total voltage loss for hours.

It can be connected via micromanipulators to microscopes and colposcopes. Special accessories can be employed, e.g. for angular cutting.

**Attachments/Accessories:**

The **Unica 315 M CO<sub>2</sub> Laser** is compatible with the following existing legally marketed Reliant Technologies, Inc. laser attachments and accessories:

1. UniMax Model 2000 Color Corrected MicroSpot CO<sub>2</sub> Laser Micromanipulator - K920821.
2. Acutome 2000 Color Corrected Laparoscopic CO<sub>2</sub> Laser Coupler and Sleeves - K942868.
3. Acutome 100 Color Corrected CO<sub>2</sub> Laser Handpiece - K942931.
4. AccuScan Model C CO<sub>2</sub> Laser Scanner - K953670.

**6. Applicant Name & Address:**

Reliant Technologies, Inc.  
1153 Triton Drive, Suite C  
Foster City, CA 94404  
415.570.6831 - 415.377.0887 (fax)

**7. Company Contact:**

Ms. Lana Black  
Reliant Technologies, Inc.  
1153 Triton Drive, Suite C  
Foster City, CA 94404  
415.570.6831 - 415.377.0887 (fax)

**8. Substantially Equivalent Device(s):**

1. Luxar Corporation. LX-20SP Laser System
2. Coherent Laser Systems. System 451 CO<sub>2</sub> Laser System
3. Laser Industries. Sharplan 1020 CO<sub>2</sub> Surgical Laser System

## 9. Equivalence:

Based on the long standing history of use of CO<sub>2</sub> lasers and the operational and clinical parameters of the Unica 315 M and the referenced comparison devices, Reliant Technologies, Inc. believes that the Unica 315 M laser is substantially equivalent to devices presently legally marketed in the US.

## 10. Feature Comparison Table:

SPECIFICATION	UNICA 315M R/G CO <sub>2</sub> Laser System	Luxar - LX-20SP Laser System	Coherent System 451 CO <sub>2</sub> Laser System	Sharplan 1020 CO <sub>2</sub> Surgical Laser System
LASER MEDIUM - WAVELENGTH:	CO <sub>2</sub> -10.6 micron			
BATTERY BACKUP:	1-5 hours depending on laser output power	NA	NA	NA
OUTPUT POWER:	1-15 Watt	2 - 20 Watt	0.5 - 100 Watt	1-20 Watt
MODE:	TEM <sub>00</sub> , Gaussian	TEM <sub>01</sub> , Multimode	TEM <sub>00</sub> , Gaussian	TEM <sub>00</sub> , Gaussian
EXPOSURE TIMES:	Single pulse and variable, 0.05 -continuous sec.			
POWER REQUIREMENTS:	110-120 VAC or 220-240 VAC	110-120 VAC or 220-240 VAC	117-220 VAC	120 VAC
AIMING BEAM:	635 nm GaAlAs - up to 5 mW 532 nm up to 3 mW	NA	HeNe 0.8 mW- 632.8 nm	HeNe 2.0 mW- 632.8 nm
BEAM DELIVERY:	Articulated arm & accessories	Hollow waveguide	Articulated arm & accessories	Articulated arm & accessories
WEIGHT:	33 lb./15 Kg.	40 lb./18.4 kg	350 lb./160 kg	80 lb./36 Kg
COOLING:	Air Cooled	Air Cooled	Water	Water
INDICATIONS:	Cutting, coagulation, excision and ablation of soft tissue.	Cutting, coagulation, excision and ablation of soft tissue.	Cutting, coagulation, excision and ablation of soft tissue.	Cutting, coagulation, excision and ablation of soft tissue.
K NUMBERS:	Pending	K953074	K951812	K860087



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20856

SEP 25 1997

Ms. Lana Black  
Vice President and Official Correspondent  
Reliant Technologies, Inc.  
1153 Triton Drive, Suite C  
Foster City, California 94404

Re: K971821  
Trade Name: Unica 315M R/G - CO<sub>2</sub> Surgical Laser System  
Regulatory Class: II  
Product Code: GEX  
Dated: August 21, 1997  
Received: August 22, 1997

Dear Ms. Black:

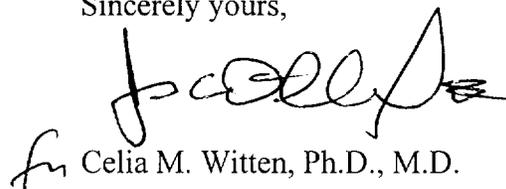
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirements, 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "M".

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

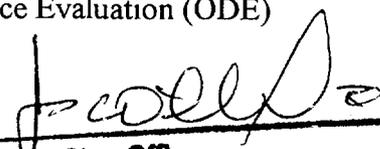
K971821

Indication for Use

The Unica 315M R/G is indicated for use as a surgical instrument to vaporize, incise, excise, ablate or photocoagulate soft tissue in general surgical procedures

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K971821

Prescription Use   
(Per 21CFR§801.109)

OR

Over-The-Counter Use  
\_\_\_\_\_