



K970143

**CLINICON CORPORATION CARLSBAD CALIFORNIA**

OCT 29 1997

**510(k) Summary**

Submitter: Clinicon Coporation

Address: 2260 Rutherford Road  
Carlsbad, CA 92008

Phone number: 619-930-0010

Fax number: 619-930-0074

Contact person: Alan Bunting

Date prepared: January 9, 1997

Trade name: C<sup>4</sup>

Common name: Laser

Classification name: Class II

Substantial equivalence claimed to:

1. Sharplan 20C - K963229
2. JMED CHRYS - K913606
3. Surgical Laser Specialties Ultra MD Laser - 510k Number Unknown

**Description:**

The Clinicon C<sup>4</sup> CO<sub>2</sub> laser is a sealed, liquid and convection cooled carbon<sup>12</sup> dioxide surgical laser that is DC excited. The output of the laser is a concentrated beam of invisible infrared light at 10.6 micrometer wavelength. The laser has an output power range of 0-25 watts delivered to tissue.

The laser system is fitted with a surgical hand piece as a standard accessory, producing a collimated beam with a spot size of 200 microns.

The hand piece is manufactured from 304 surgical stainless steel.

**Intended use:**

For use in vaporization, incision and excision of soft tissue in dermatology, general surgery, neurosurgery, oral surgery, oto-rhino-laryngology, and podiatry.

**Summary of technological characteristics:**

The Clinicon C<sup>4</sup> CO<sub>2</sub> Surgical Laser energy is delivered to the surgical site via an articulated arm. The substantially equivalent devices are delivered either by an articulated arm or a hollow flexible waveguide.

The Clinicon C<sup>4</sup> CO<sub>2</sub> Surgical Laser's surgical beam wavelength is in the (invisible) infrared region of the spectrum, at 10.6 micrometers (microns). The substantial equivalent devices are 10.6 micron wavelength.

**Handpieces**

HANDPIECE K 50R Surgical Handpiece straight.

Focal length 2"

HANDPIECE K 100R Surgical handpiece straight.

Focal length 4"

HANDPIECE K 100RO Surgical handpiece straight.

Focal length 4" (OPEN CANNULA)

HANDPIECE K 100A Surgical Handpiece Angled.

Focal length 4"

HANDPIECE K 100B Surgical Handpiece with backstop.

Focal length 4"

HANDPIECE K 125B Surgical handpiece with backstop.

Focal length 5"

**Manipulator**

MICROMANIPULATOR KM Ring adapters available for most popular colposcopes and microscopes.

MICROMANIPULATOR KMC Ring adapters available for most popular colposcopes and microscopes (Central mirror)



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Fritz A. Brauer  
President  
Clinicon Corporation  
2260 Rutherford Road  
Carlsbad, California 92008

OCT 29 1997

Re: K970143  
Trade Name: C<sup>4</sup> CO<sub>2</sub> Laser  
Regulatory Class: II  
Product Code: GEX  
Dated: August 13, 1997  
Received: August 18, 1997

Dear Mr. Brauer:

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.

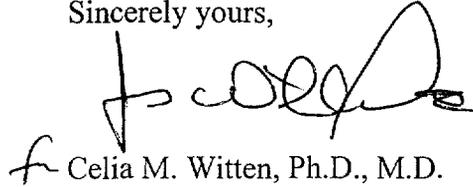
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Fritz A. Brauer

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,



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): K970143

Device Name: C<sup>4</sup> CO<sub>2</sub> laser

AUG 18 12 43 PM '97

Indications for Use:

For use in vaporization, incision and excision of soft tissue in dermatology, general surgery, neurosurgery, oral surgery, oto-rhino-laryngology, and podiatry.

The Clinicon C<sup>4</sup> CO<sub>2</sub> laser is a sealed, liquid and convection cooled carbon dioxide surgical laser that is DC excited. The output of the laser is a concentrated beam of invisible infrared light at 10.6 micrometer wavelength. The laser has an output power range of 0-25 watts delivered to tissue.

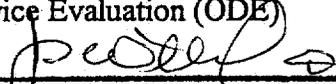
The laser system is fitted with a surgical hand piece as a standard accessory, producing a collimated beam with a spot size of 200 microns. The hand-pieces sold with this device will be of the same design and configuration but will have various tip sizes and focal lengths.

These hand pieces are only intended for open surgery procedures in the non-contact mode.

The hand piece is manufactured from 304 surgical stainless steel.

(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 K970143

Prescription Use X

OR

Over-the-Counter Use \_\_\_\_\_