Certified Software Solutions, Inc.

K063698

510(k) Summary

Submitter/Applicant Name:	Clinicon Corporation
Contact:	Fritz Brauer
Address:	3025-A Industry Street Oceanside, CA 92054
Phone number:	(760) 439-1700
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MAR 0 2 2007

Contact person:	Kim L. Bloom (CSS, Inc.)
Phone number:	(858) 675-8200
Fax number:	(858) 675-8201

Date prepared:	December 11, 2006
Trade name:	C_Las CO_2 Laser System
Common name:	CO_2 Laser System
Classification name:	II

Substantial equivalence claimed to:

K 875338: CHRYS (20 Watt CO_2 Laser, cleared on April 13, 1988. The CHRYS (20 Watt CO_2 Laser was cleared as a laser surgical instrument for use in general surgery as well as plastic surgery and in dermatology.

Device Description

The CO_2 Laser System, Model C-LAS is an easily transported table top laser console made of mainly machined aluminum and optics for the transmission of reflection of CO_2 laser wave lengths. It is a carbon dioxide laser which emits laser light at 10.6 micrometers and has a RF excited laser tube which produces an output power of about 30 watts. The laser is for used by physicians for cutting and coagulation at a wound during surgery. The physician uses the laser light on tissue via lenses and a focusing hand piece, or via a diamond scalpel which transmits the laser light onto the scalpel.

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Intended Use

The CO_2 Laser, Model C-LAS is intended to be used by physicians for soft tissue cutting and tissue ablation in the following specialties:

- Cosmetic Surgery
- Dermatology
- General Surgery
- Gynecology
- Head & Neck Surgery
- Neurosurgery
- Oral Surgery
- Orthopedic Surgery
- Otorhinolaryngology
- Pediatric Surgery
- Plastic & Reconstructive Surgery
- Podiatry
- Urology

General Product Information

1. Product Names: A.R.C. CO_2 Laser System
2. Regulatory Information
    a. Regulatory Section: 878.4810
    b. Classification: Class II
    c. Product Code: GEX
    d. Panel: General & Plastic Surgery
3. Intended Use:
    a. Indication(s) for use: Please see page 9 and 12.
    b. Special conditions for use statement(s): N/A
    c. Special instrument requirements: N/A
4. Device Description: Please see 510k Summary page 8.
5. Standard/Guidance Document Referenced: Please see pages 20
6. Performance Characteristics: Please see the Software Test Procedures and Test Report.
7. System description: Please see the Operational's Manual.
8. Product Safety Standards and Test Results: Please see Certificate of Conformity attachment and Software Test Procedures.

Supporting specifications:
Please see attached validation documents (some of which may also be noted on the last page of this document):

1) **Certificate of Conformity**
2) **Safety Risk Analysis**
3) **Software Requirements Specification**
4) **Software Test Procedures**
5) **Software Test Report**
6) **C-Las Brochure**
7) **C-Las Operator's Manual**

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Technological Similarities and Differences to Predicate

Substantial equivalence claimed to:
K875338: CHRYS™ MODEL MED-MAX cleared on 04/13/1988 as a laser surgical instrument for use in general surgery as well as plastic surgery and in dermatology.

Summary of technological characteristics:
The following table describes similarities between CO_2 Laser, Model C-LAS and the California Laboratories CHRYS™ MODEL MED-MAX (the predicate).

Similarities		
Item	**Device**	**Predicate**
Name	CO_2 Laser, Model C-LAS	CHRYS™ MODEL MED-MAX by California Laboratories (K875338)
Intended use	Intended to be used by physicians to cut and coagulate wounds during surgery.	Intended to be used by physicians to cut and coagulate wounds during surgery.
Footprint	Compact 12.5"x 13"	Compact 15" by 20"
Laser	CO_2 sealed	CO_2 sealed
WaveLength	10.6 micrometers	10.6 micrometers
Mode	Continuous wave form (Gauss)	Continuous wave form (TEM00)
Accessories	Flexible Cable Waveguide	Articulated Arm Waveguide
Output Power	About 30 Watts	About 30 Watts
Weight	39.6 pounds	45 pounds
Console	Microprocessor	Microprocessor
Laser Operation	Footswitch	Footswitch

Based on the intended use and the use of laser technology for cutting and coagulation of wounds during surgery using a waveguide, the CO_2 Laser is substantially equivalent to the California Laboratories CHRYS.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Clinicon Corporation
% Certified Software Solutions, Inc.
Ms. Kim L. Bloom
Sr. Software Quality Engineer
16787 Bernardo Center drive, Suite A-1
San Diego, California 92128

MAR 0 2 2007

Re: K063698
Trade/Device Name: CO_2 Laser, Model C-LAS
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: February 14, 2007
Received: February 15, 2007

Dear Ms. Bloom:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

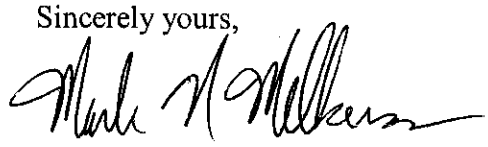
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

Indications for Use
510(k) Number: _____(To be determined)
Device Name: C_Las CO_2 Laser System

Indications for Use: The CO_2 Laser, Model C-LAS is intended to be used by physicians for soft tissue cutting and tissue ablation in the following specialties:

- Cosmetic Surgery
- Dermatology
- General Surgery
- Gynecology
- Head & Neck Surgery
- Neurosurgery
- Oral Surgery
- Orthopedic Surgery
- Otorhinolaryngology
- Pediatric Surgery
- Plastic & Reconstructive Surgery
- Podiatry
- Urology

Prescription Use ___X___ AND/OR Over-the-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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, and Neurological Devices

510(k) Number K063968

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