

K964831

CLINICON CORPORATION CARLSBAD CALIFORNIA

AUG - 8 1997

510(k) Summary

Submitter: Clinicon Corporation
2260, Rutherford Road, Suite 101
Carlsbad, CA 92008

Phone Number: 619 930 0010

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Contact Person: Alan Bunting

Date Prepared: November 26th, 1996

Trade Name: SureScan

Common Name: Laser Accessory

Classification Name: Class II

Substantial Equivalence
Claimed To:

1. Hexascan - Lithan Techn. Inc. 510(k) # K 901008
2. CPG - Coherent Medical Inc 510(k) # not known
3. SureScan - Clinicon Corp. 510(k) # K 962242

Description:

SureScan adapts to laser systems with wavelengths in the visible spectrum from 430nm to 700nm (blue, green, yellow and red) and to lasers in the invisible spectrum from 755nm to 2940nm to deliver precise amounts of energy to tissue.

SureScan comes equipped with multiple treatment patterns in multiple sizes. SureScan is programmable to enable adjustment of scan speed across tissue to ensure uniform laser absorption or ablation which significantly reduces thermal damage and thus the potential for post operative scarring.

SureScan also has an adjustable spot overlap density and scanner dwell time feature which allows the surgeon to select individual treatment parameters most suitable for various tissue types and lesions.

Pattern outline and size are clearly displayed on tissue, allowing precise placement of the laser energy and alignment of subsequent scan shapes.

Indications for Use:

Wavelength range 430-1064 Nanometer

In this wavelength range, SureScan is designed to assist in the partial or full coagulation or denaturation of a variety of benign epidermal vascular and pigmented lesions where precise dosimetry is required to minimize damage to adjacent or underlying tissue layers. SureScan use is restricted for adaptation to those lasers that have received FDA clearance for applications in cutaneous laser surgery for the treatment of benign superficial vascular and pigmented lesions such as port wine stains angiomas, telangiectasia, café-au-lait marks, age spots, lentigines, tattoos and similar conditions.

Wavelength range 1440-10640 Nanometer

In this wavelength range, SureScan is designed to assist in a variety of procedures that require the ablation of soft tissue, where precise removal is required to minimize damage to adjacent or underlying tissue layers. SureScan use is restricted for adaptation to those lasers that have received FDA clearance for soft tissue ablation, such as scars, keloids, warts, skin malformations and similar conditions.

Technical Description

SureScan employs a microprocessor controlled, mirror system for scanning the laser beam. SureScan juxtaposes laser beam spots with precisely controlled timing and predetermined amounts of space in between or with spatial overlap of these spots. Depending on the type of laser used and its wavelength, highly controlled tissue coagulation or ablation is achieved with minimal thermal injury.

SureScan's operation is controlled via an existing laser foot switch, to eliminate any adjustment of the internal electronics or workings of the laser. To ensure precise transmission of the laser beam through the SureScan device and subsequent safe delivery of laser energy to tissue, a user controlled adjustment feature allows for realignment of the laser beam due to a misaligned fiber or other delivery system as it is directed through the SureScan hand piece.

As a result, the operator is always assured of optimum beam quality without 'clipping', as the laser beam exits the SureScan hand piece.

Different sized squares, rectangles, triangles, hexagons, parallelograms and lines may be selected and are outlined by the laser systems pilot laser. These various patterns are then automatically covered by the therapeutic laser and coagulate, denaturize or ablate tissue in a single scan cycle. This results in a more predictable and controlled tissue effect to optimize treatment results.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

AUG - 8 1997

Re: K964831
Trade Name: SureScan
Regulatory Class: II
Product Code: GEX
Dated: May 9, 1997
Received: May 12, 1997

Dear Dr. Brauer:

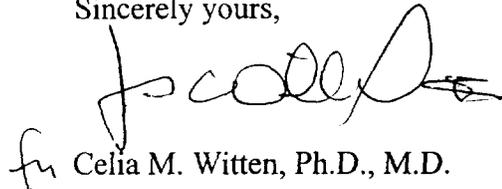
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

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', with a stylized flourish at the end.

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): K 9648 31
 Device Name: SureScan
 Indications for Use:

CAUTION

SureScan use is restricted for adaptation to laser systems that have received FDA clearance for cutaneous surgical applications and soft tissue ablation at the following specific wavelengths: 488nm, 511nm, 514nm, 520nm, 530nm, 532nm, 568nm, 577nm, 578nm, 585nm, 694nm, 752nm, 1064nm, 2940nm. Users should refer to the laser manufacturer's operating manual for applications that have been cleared for the specific wavelength.

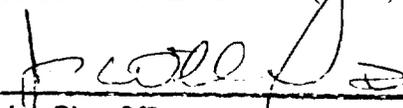
SureScan Wavelengths & Indications for Use

(Consult Manufacturer's Manual for Cleared Applications)

488nm	Blue/Green	CW Argon	Epidermal vascular lesions
511nm	Green	Pulsed Copper Vapor	Epidermal vascular lesions
514nm	Green	CW Argon	Epidermal vascular lesions
520nm	Green	CW Krypton	Epidermal vascular lesions
530nm	Green	CW Krypton	Epidermal vascular & Pigm. Lesions
532nm	Green	CW/Pulsed KTP YAG	Epidermal vascular & Pigm. Lesions
568nm	Yellow	CW Krypton	Epidermal vascular & Pigm. Lesions
577nm	Yellow	CW Dye	Epidermal vascular & Pigm. Lesions
578nm	Yellow	Pulsed Copper Vapor	Epidermal vascular & Pigm. Lesions
585nm	Yellow	CW Dye	Epidermal vascular & Pigm. Lesions
694nm	Red	Pulsed Ruby	Epid. Pigm. Lesions & Tattoos
752nm	Red	Pulsed Alexandrite	Epid. Pigm. Lesions & Tattoos
1064nm	IR	Pulsed Nd:YAG	Epidermal Pigmented Lesions
2940nm	IR	CW Er:YAG	Soft Tissue Ablation

(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 K964831

Prescription Use
 (Per 21 CFR 801.109)

OR

Over-the-Counter Use

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