

JUL 8 1998

K980501

**FULLER RESEARCH CORPORATION**944 Morgan Road Rydal, PA 19046 (215) 885-4558 Fax (215) 885-2788
FULLERTA@AOL.COM**PREMARKET NOTIFICATION [510(k)] SUMMARY**

As required by section 807.97(c)

Submitted by: Joseph A. Muccini, M.D.
Medical and Regulatory Director

Contact: Joseph A. Muccini, M.D. or
Terry A. Fuller, Ph.D.

Date Prepared: June 17, 1998

510(k) Number: K980501

Trade or Proprietary Name: SkinLaser

Common or Usual Name: Surgical/Medical Solid State Laser System

Equivalence:

The SkinLaser System is substantially equivalent to continuous wave (CW) and pulsed CW surgical lasers in the wavelength range of 800nm to 1064nm. Such systems have been in surgical use for many years offering broad multi-specialty, multi-procedure applications. The laser deliver system includes both contact and non-contact devices. The following chart is a partial list of equivalent products currently marketed by other manufacturers.

| Company | Model / Power | Wavelength, Aiming beam wavelength | Other |
|-------------------------------|-------------------------------|------------------------------------|--|
| Fuller Research Corporation | SkinLaser ST-25 25W laser | 800-980nm, 655nm aiming beam | Proprietary fiber connector, CW & Pulsed, internal cooling system, |
| Surgimedics, Diomed, Ltd. | Diomed 15W, 25W and 60W laser | 780 - 830nm, 650nm aiming beam | SMA fiber connector, CW & pulsed, internal cooling system |
| Applied Optronics Corporation | AOC-25, 25W laser | 980nm, 655nm aiming beam | SMA fiber connector, CW & Pulsed, internal cooling system |
| Indigo Medical, Inc. | Indigo 830, 20W laser | 830nm, 670nm aiming beam | SMA fiber connector, CW & Pulsed, internal cooling system |
| Endocare Medical | DioLase 60, 60W laser | 950-1010nm, red aiming beam | SMA fiber connector, CW & Pulsed, internal cooling system |

The function and features of the SkinLaser System is equivalent to or identical to currently marketed devices. Thus, the SkinLaser System is not a "new" device and can be marketed for the Indications for Use as systems currently marked.

PREMARKET NOTIFICATION [510(k)] SUMMARY (Continued)

Indications for Use include:

The SkinLaser System is indicated for incision, excision, coagulation and vaporization of soft tissue.

In general surgery, dermatologic and plastic surgery, all soft tissues are included in this indication: skin, subcutis, breast, abdominal and striated and smooth muscle, tendon and fascia, cartilage, mucous membrane, lymph vessels and nodes, and internal organs and glands.

In gynecologic and urologic surgery indications include endoscopic, intra-abdominal and externally accessed (free-hand) gynecological and urological tissues, structures, obstructions, strictures, tumors, and other lesions. Only palliative treatment and partial removal of neoplastic tissue should be assumed.

In gastroenterology indications include destruction of polyps, lesions, varices, tumors, and for treatment of hemorrhages.

In pulmonology surgery indications include flexible or a rigid endoscopic and free-hand access and treatment of soft tissue lesions, obstructions, tracheal stenosis, and tumors.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Terry A. Fuller, Ph.D.
•President
Fuller Research Corporation
944 Mogan Road
Rydal, Pennsylvania 19046

Re: K980501
Trade Name: Skin Laser System
Regulatory Class: II
Product Code: GEX
Dated: May 27, 1998
Received: May 29, 1998

Dear Dr. Fuller:

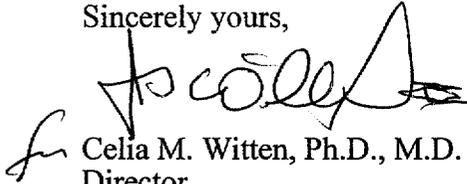
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

Page 2 - Dr. Terry Fuller

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 "C. Witten", is written over the typed name. The signature is fluid and cursive.

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: K980501
Device Name: SkinLaser System

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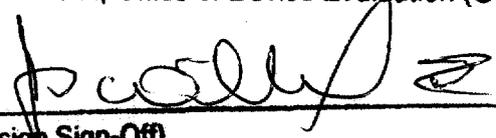
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980501

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)