

SEP 27 2012

**510(k) Summary for the  
Lutronic Corporation FREEDOM Laser System**

This 510(k) Summary is being submitted in accordance with the requirements of the  
SMDA 1990 and 21 CFR 807.92.

**1. General Information**

Submitter: Lutronic Corporation  
Room 403-1, 2, 3, 4, 5, 404 Ilsan Technotown  
1141-1 Baekseok-dong, Ilsandong-gu,  
Goyang-si, Gyeonggi-do, 410-722  
Republic of Korea

Contact Person Jhung Won Vojir, Ph.D.  
Chief Executive Officer  
Lutronic, Inc.  
Six Neshaminy Interplex, Suite 207  
Trevose, PA 19053  
[jvojir@lutronic.com](mailto:jvojir@lutronic.com)  
Tele: 215-205-2219  
FAX: 609-488-6958

Summary Preparation Date: December 27, 2011

**2. Names**

Device Name: FREEDOM Laser System

Classification Name: Laser instrument, surgical, powered device:  
GEX  
FDA Class II category

**3. Predicate Devices**

The FREEDOM Laser System is substantially equivalent to the Cutera GenesisPlus  
(K103626).

#### **4. Device Description**

The FREEDOM Laser System consists of a self-contained console, an optical fiber delivery system and a footswitch. The system console is the heart of the FREEDOM Laser System and contains the Nd:YAG optical system, laser system control, fiber delivery system with handpiece, system control module with an embedded processor, and power supply module. The main console also includes a key switch used to turn the power on and off, an emergency stop push button that quickly de-energizes the system in emergency situations, and the LCD display.

#### **5. Indications for Use**

The FREEDOM Laser System is intended for the following:

Intended for use in the medical specialties of general and plastic surgery, dermatology, endoscopic, laproscopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, pulmonarythoracic surgery, podiatry and urology for surgical and aesthetic applications.

For intended use in Dermatology for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, rosacea, poikiloderma of civatte, and treatment of benign cutaneous lesions, such as warts, scars and striae. Also intended for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.

For intended use on all skin types (Fitzpatrick I-VI), including tanned skin.

For intended use in Podiatry for the ablation, vaporization, incision, excision, and coagulation of soft tissue, including Matrixectomy, Periungual and subungual warts, Plantar warts, Radical nail excision, Neuromas.

For intended use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes, Trichophyton rubrum and T. mentagrophytes, and/or yeast Candida Albicans, etc.).

#### **6. Substantial Equivalence**

The FREEDOM Laser System is substantially equivalent to the Cutera GenesisPlus (K103626). The intended use and technological characteristics of the FREEDOM Laser System are identical to the intended use and technological characteristics of the predicate devices. Therefore, the FREEDOM Laser System is substantially equivalent the predicate device.

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**7. Performance Data**  
None presented.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

May 13, 2013

Lutronic Corporation  
% Lutronic Incorporated  
Ms. Jung Won Vojir  
Global Regulatory Officer  
6 Neshaminy Interples, Suite 207  
Trevose, Pennsylvania 19053

Re: K113843

Trade/Device Name: FREEDOM Laser System

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and  
plastic surgery and in dermatology

Regulatory Class: Class II

Product Code: PDZ, GEX

Dated: September 5, 2012

Received: September 6, 2012

Dear Ms. Vojir:

This letter corrects our substantially equivalent letter of September 27, 2012.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,  
FOR

**Peter D. Rumm -S**

Mark N. Melkerson  
Acting Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known): K113843

Device Name: FREEDOM Laser System

**Indications for Use:**

Intended for use in the medical specialties of general and plastic surgery, dermatology, endoscopic, laproscopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, pulmonarythoracic surgery, podiatry and urology for surgical and aesthetic applications.

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Prescription Use X  
(Part 21 CFR 801 Subpart D)  
Subpart C)

AND/OR

Over The Counter Use     
(Part 21 CFR 801

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Neil K. Byle for mkm  
(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices