OCT 0 8 2008

510(k) Summary for the
Lutronic Corporation PowerLipo Laser System K082096

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 #403-2,3,4, Ilsan Technotown 1141-1 Baeksok-Dong, Ilsan-Gu Goyang-Si, Gyeonggi-Do, 410-722 Republic of Korea
Contact Person:	Maureen O'Connell O'Connell Regulatory Consultants, Inc. 5 Timber Lane North Reading, MA 01864 Telephone: 978-207-1245 Fax: 978-824-2541
Summary Preparation Date:	July 21, 2008

2. **Names**

Device Name:	PowerLipo Laser System
Trade Name:	PowerLipo
Classification Name:	Laser Instrument, Surgical, Powered Product Code: GEX Panel: General & Plastic Surgery

3. **Predicate Devices**
The PowerLipo Laser System is substantially equivalent to a combination of the SmartLipo Laser System, the SmartLipo Multiwavelength Laser System, the Cynosure YAG MIR II Laser and the CoolTouch NS160 CoolLipo Nd:YAG Surgical Laser.

4. **Device Description**
   The PowerLipo Laser System consists of a self-contained console, an optical fiber delivery system and a footswitch. The system console is the heart of the PowerLipo 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 FND display.

5. **Indications for Use**
   The PowerLipo Laser System is indicated for use the surgical incision, excision, vaporization, ablation, and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. The PowerLipo is further indicated for laser assisted lipolysis.

6. **Performance Data**
   None presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 8 2008

Lutronic Corporation
% O'Connell Regulatory Consultants, Inc.
Ms. Maureen O'Connell
5 Timber Lane
North Reading, MA 01864

Re: K082096
Trade/Device Name: PowerLipo Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Instrument, Surgical, Powered
Regulatory Class: Class II
Product Code: GEX
Dated: July 21, 2008
Received: July 24, 2008

Dear Ms. O'Connell:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (if known): K082096

Device Name: PowerLipo Laser System

Indications for Use:

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Prescription Use X AND/OR Over The Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 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 K082096