DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 6 2009

Energist, Ltd.
% Mr. Tim Major
Engineering Director
Clos Llyn Cwm, Valley Way
Enterprise Park, Swansea, SA6 8QY
United Kingdom

Re: K082825
Trade/Device Name: Energist ULTRAPLUS™ VPL Intense Pulsed Light System
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: December 4, 2008
Received: December 8, 2008

Dear Mr. Major:

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) 276-0115. 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): K082825

Device Name: Energist ULTRAPLUS™ VPL Intense Pulsed Light System

Indications for Use:

The Energist ULTRA™ VPL Intense Pulsed Light System is intended for permanent hair reduction and the treatment of mild to moderate inflammatory Acne Vulgaris. It is also indicated for photocoagulation of dermatological vascular lesions, photothermolysis of blood vessels and the treatment of benign pigmented lesions.

- Intense Pulsed Light Energy / wavelengths (530 – 950nm)

  The 530 – 950nm intense pulsed wavelengths are indicated for:
  The treatment of mild to moderate inflammatory Acne Vulgaris.
  The treatment of benign pigmented epidermal and cutaneous lesions including warts, scars and striae.
  The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasma, angiomas and spider angiomas, Poikiloderma of Civatte, leg veins, facial veins and venous malformations.

- Intense Pulsed Light Energy / wavelengths (610 – 950nm)

  The 610 – 950nm intense pulsed wavelengths are indicated for:
  The removal of unwanted hair from all skin types and to effect stable long-term or permanent[*1] hair reduction in skin types I – V through selective targeting of melanin in hair follicles.

[*1] Permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after a treatment regimen.

- Intense Pulsed Light Energy/wavelengths (415/630 – 950nm)
  The treatment of mild to moderate inflammatory Acne Vulgaris.

(Over)

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