Section 5 – 510(k) Summary

This 510(k) summary of safety and effectiveness for the Energist ULTRA variable pulsed light system has been prepared in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990 and follows relevant Office of Device Evaluation (ODE) guidance concerning the organisation and content of a 510(k) summary.

5.1 Applicant
Energist Ltd

5.2 Address
2 Clos Llyn Cwm , Enterprise Park, Swansea SA6 8QY, UK

5.3 Contact Person
Peter Smith, Engineering & Regulatory Affairs Manager
Tel: +44 (0)1792 798768 Fax: +44 (0)1792 762099

5.4 Preparation Date
January 19, 2006

5.5 Device Trade Name
Energist ULTRA Variable Pulsed Light (VPL™) System

5.6 Device Common Name
Intense Pulsed Light System

5.7 Device Classification
Laser surgical instrument for use in General and Plastic Surgery and Dermatology
Product code: GEX
21 CFR 878.4810

5.8 Legally marketed Predicate Devices
McCue Energist ULTRA™, K040659
Cyden IFL Professional System, K050165

5.9 Device Description
The Energist ULTRA VPL™ System is a light based medical device that delivers a beam of pulsed non-ionising radiation in the region of 530nm to 950nm. The system is designed to be compact and self contained and includes the following features:

- Control console unit
- Display panel
- Power supply
- Cooling system
- Removable handpiece with integrated switch, lamp, filter and glass coupling block

5.10 Intended 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.

5.11 Comparison of Technological Characteristics

The Energist ULTRA VPL System has an identical intended use to the McCue predicate system and identical technological characteristics except for modifications to the device software and high voltage component. These differences do not result in differences in performance or raise new questions of safety and efficacy. The Energist ULTRA VPL System also has the same principles of operation, mode of action and equivalent energy outputs that are used by the Cyden predicate device to achieve the treatment of Acne Vulgaris. Performance data was provided to demonstrate that the system is capable of providing the outputs necessary to achieve its required treatment parameters. The Energist ULTRA VPL™ System is therefore concluded to be substantially equivalent to both of the above named predicate devices and minor differences to the systems do not raise additional concerns of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2006

Energist, Ltd.
c/o Mr. Peter Smith
Engineering & Regulatory Affairs Manager
2 Clos Llyn Cwm Enterprise Park
Swansea City and County of Swansea SA6 AQY
United Kingdom

Re: K060216
Trade/Device Name: Energist ULTRA™ VPL Intense Pulse 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: January 19, 2006
Received: January 27, 2006

Dear Mr. Smith:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Acting 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): K060216

Device Name: Energist ULTRA™ VPL Intense Pulse 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.

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(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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices