EXHIBIT #1

MAY - 9 2003

510(K) SUMMARY K030423

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA I990 and 21 CFR §807.92.

The assigned 5l0(k) number is:_____.

1. **Submitter's Identification:**

   Preswede AB
   Humlegatan 15
   501 10 Boras, Sweden

   Date Summary Prepared: February 6, 2003

2. **Name of the Device:**

   Powerlite 600® EP System.

3. **Predicate Device Information:**

   K#963249, Epilight™ Hair Removal System, ESC Medical Systems, Yokneam Industrial Park, Yokneam 20692, ISRAEL.

4. **Device Description:**

   The Powerlite 600® EP System delivers pulsed light at a wavelength beginning at a wavelength of 600nm. The device consists of three interconnected sections: the system console which houses the internal cooling system, power supply and micro-controller, the handle hose to the handpiece, and the handpiece, which houses the waveguide.

5. **Intended Use:**

   The Powerlite 600® EP System is used for the removal of unwanted hair.

6. **Comparison to Predicate Devices:**

   The Powerlite 600® EP and the Epilight devices are very similar or identical in terms of the device structure and its technology. Both systems are electro-optical medical devices designed for effective photothermal treatment of unwanted hair and its removal. Both devices deliver intense pulsed light, broad spectrum light, starting from 590nm or 600nm, with sufficient energy to be absorbed in the hair follicles and penetrate deeply enough and at a temperature high enough to denature and impair hair growth without damaging surrounding skin.

A main difference between Powerlite 600® EP and Epilight devices is the type of control terminal. The Powerlite 600® EP System is LCD touch panel controlled, while the Epilight system is terminal –controlled.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Electrical and EMC testing per IEC 60601-1 and IEC 60601-1-2 requirements

8. **Discussion of Clinical Tests Performed:**

Non-Applicable

9. **Conclusions:**

The Powerlite 600® EP System has the same intended use and similar characteristics as the Epilight™ Hair Removal System. Moreover, documentation supplied in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Powerlite 600® EP System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2003

Preswede AB
c/o Ms. Susan Goldstein-Falk
MDI Consultants, Inc.
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K030423
Trade/Device Name: Powerlite 600® EP 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: February 6, 2003
Received: February 10, 2003

Dear Ms. Goldstein-Falk:

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 (301) 594-4659. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K030423

Device Name: Powerlite 600® EP System

Indications For Use:

The Powerlite 600® EP System is used for the removal of unwanted hair.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The Counter Use_____ (Optional Format 1-2-96)

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K030423