DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 8 2004

Ms. Anne Worden
Regulatory Consultant
MSq($M^2$) Ltd.
c/o A.Worden Consulting
3637 Bernal Avenue
Pleasanton, California 94566

Re: K033946
Trade/Device Name: Lovely System Models: Lovely I (Aria) & Lovely II (Harmony)
Regulation Number: 21 CFR 878.4810 and 21 CFR 878.4630
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology and Ultraviolet lamp for dermatologic disorders
Regulatory Class: II
Product Code: GEX and FTC
Dated: December 16, 2003
Received: January 9, 2004

Dear Ms. Worden:

This letter corrects our substantially equivalent letter of April 5, 2004 regarding the Indications of Use.

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. 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 Miriam C. Provost

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
New Indications for Use

## INDICATIONS FOR USE

**510(k) Number (if known):** K033946

**Device Name:** Lovely System Models: Lovely I (Aria) & Lovely II (Harmony)

**Indications for Use:**

The Lovely System models (Aria and Harmony) are intended for use in aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of plastic surgery and dermatology as follows:

Lovely I (Aria) & Lovely II (Harmony) Models:
The Advanced Fluorescence Technology (AFT) with 420-950 nm wavelengths is indicated for:

- The treatment of moderate inflammatory acne vulgaris.
- The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles).
- The treatment of 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, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The removal of unwanted hair and to effect stable long-term or permanent hair reduction.

Lovely II (Harmony) Model:
The Nd:YAG lasers (1064nm) are indicated for:

- The removal of black, blue or green tattoos.
- Coagulation and hemostasis of vascular lesions and soft tissue, including treatment and clearance of superficial and deep telangiectasias (venulectasias) and reticular veins (0.1-4.0 mm diameter) of the leg.
- The non-ablative treatment of facial wrinkles.

Lovely II (Harmony) Model:
The UVB Light source (300-380nm) is indicated for:

- The treatment of leukoderma, including vitiligo (acquired leukoderma).
- The treatment of psoriasis, atopic dermatitis (eczema), and seborrheic dermatitis.

The Lovely System models are also indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)

**510(k) Number** K033946



Page Revised March 30, 2004

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## 510(K) SUMMARY

# LOVELY SYSTEM

**510(k) Number K** 033946

**Applicant's Name:** MSq($M^2$) Ltd.
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Caesarea Industrial Park 38900 Israel
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**Contact Person:** Arava Hacohen
Push-med Ltd.
117 Ahuzah St.
Ra'anana 43373, Israel
Tel: 972-9- 7718130
Fax: 972-9-7718131
e-mail: arava@push-med.com

**Date Prepared:** December 2003

**Trade Name:** Lovely System

**Classification Name:** Laser Instrument, Surgical, Powered

**Classification:** FDA has classified laser device as a class II device (product code GEX) and it is reviewed by the General & Plastic Surgery Panel.

**Predicate Devices:** The Lovely System is substantially equivalent in terms of technological characteristics, performance, intended use, indications for use and operator interface to the following predicate devices:

- Lumenis Family of Intense Pulse-Light (IPL) and IPL/ND:YAG Laser Systems ("Lumenis Combined IPL") cleared under K030342, K030527and K024093.
- Estelux™ (Palomar Medical Technologies) cleared under K020453.
- Altus Medical Family of Altus Medical CoolGlide Aesthetic Lasers with Optional Pulse Light Handpiece ("CoolGlide") cleared under K023954.
- ClearLight Phototherapy Device, Model CL420 ("ClearLight") (CureLight Ltd) cleared under K013623 and K030338.
- Bclear™ (Lumenis, Inc.) cleared under K020591 and K021762.

- Medlite Q-Switched Laser ("Medlite") (Continuum Electro-Optics, Inc.) cleared under K970808, K973719, K983054, K011677, K014234 and K022709.

**Performance Standards:**

The Lovely Diode Laser complies with:U.S. Federal Performance Standards 21 CFR 1040.10 and 21 CFR 1040.11 for class IV Laser Products.
In addition, the device complies with the European Medical Directive 93/42/EEC concerning medical devices (Annex II) and with the voluntary standards IEC 60601-1, IEC 60601-1-2, IEC-60825-1 and IEC 601-2-22.

**Intended Use / Indication for Use:**

The Lovely System is intended for use in aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of plastic surgery and dermatology as follows:

The Applied Fluoresce Technology (AFT) with 420-950nm wavelengths is indicated for:

- The treatment of moderate inflammatory acne vulgaris.
- The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles).
- The treatment of 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, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- The removal of unwanted hair and to effect stable long-term or permanent hair reduction.

The Nd:YAG laser (1064nm) is indicated for:

- The removal of black, blue or green tattoo.
- Coagulation and hemostasis of vascular lesions and soft tissue, including treatment and clearance of superficial and deep telangiectasias (venulectasias) and reticular veins (0.1-4.0 mm diameter) of the leg.
- The non-ablative treatment of facial wrinkles.

The UVB Light source (300-380nm) is indicated for:

- The treatment of leukoderma.

- The treatment of psoriasis, vitiligo, atopic dermatitis (eczema), leukoderma, and seborrheic dermatitis

The lovely System is indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.

**Device Description:** The Lovely is a platform for AFT, UVB and Nd:YAG Laser Technology for various Aesthetic and Cosmetic applications. The Lovely has an option to operate seven different handpieces that emits light at 300nm to 1064nm for the following applications:

- Hair removal
- Skin Rejuvenation
- Vascular and Pigmented lesion
- Moderate Acne
- Deep leg veins
- Tattoo removal
- Psoriasis and vitiligo

The system includes:

- A light/laser system console (including software and control electronics) that controls timing and dosing parameters. The console includes a water-cooling system used to remove heat from the power supply and the optical bench.
- A control and display panel including LCD and soft-keys.
- Seven optional handpiece(s) that includes the light source, electronics and pipes of the water cooling system.

**Substantial Equivalence:** The Lovely System is substantially equivalent in terms of technological characteristics, performance, intended use, indications for use and operator interface to the following predicate devices:

- Lumenis Family of Intense Pulse-Light (IPL) and IPL/ND:YAG Laser Systems ("Lumenis Combined IPL") cleared under K030342, K030527and K024093.
- Estelux™ (Palomar Medical Technologies) cleared under K020453.
- Altus Medical Family of Altus Medical CoolGlide Aesthetic Lasers with Optional Pulse Light Handpiece ("CoolGlide") cleared under K023954.
- ClearLight Phototherapy Device, Model CL420 ("ClearLight") (CureLight Ltd) cleared under K013623 and K030338.
- Belear™ (Lumenis, Inc.) cleared under K020591 and K021762.

- Medlite Q-Switched Laser ("Medlite") (Continuum Electro-Optics, Inc.) cleared under K970808, K973719, K983054, K011677, K014234 and K022709.

There are no unique applications, indications, material or specifications presented below. Evidence of equivalence has been demonstrated through:

- The Lovely intended use and indications for use were previously cleared by FDA for the predicate devices.
- The technical characteristics of the Lovely are similar to those of the predicate devices.
- Laser output values of the Lovely are well within previous cleared values of the predicate devices as described.
- The predicate devices and other previous cleared devices with similar energy output have a proven safety and effectiveness in the treatment of the claimed indications.
- Safety and performance testing.

Therefore, the Lovely System is substantially equivalent to its predicate devices cited above and raises no new safety and/or effectiveness issues.