K063249

JAN 17 2007

510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

Device Name

Proprietary Device Name: BEAMAX

Establishment Name and Registration Number of Submitter

Name: Medic SharpLight Ltd.
Registration: In process
Submission contact: Dan Laor
Sireni 6, Haifa 32972, Israel TEL: 972-4-8246632

Device Classification

Product Code:	GEX
Regulation Number:	878.4810
Common Name:	Pulsed light hair removal system
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology.
Regulatory class:	Class II

Reason for 510(k) Submission

Traditional 510(k) Submission

Identification of Legally Marketed Equivalent Devices

K033946 Lovely I (Aria)

Device Description

The BEAMAX applies thermal energy to human skin tissue. The energy is transmitted from a flash light source. It is transmitted to the target tissue by a hand piece that is in contact with the skin (contact mode).
The device is constructed from a Man Machine Interface panel, an operating console, and a treatment hand piece.

Indications for use

The BEAMAX is intended for aesthetic and cosmetic use. The device is specifically indicated for removal of hair by using selective light energy.

Safety & Effectiveness

The device has been designed, verified and validated complying with the 21CFR 820.30 regulations. Bench and clinical data demonstrate that the BEMAX meets the required specifications. No adverse affects have been detected.

Substantial Equivalency

It is Medic SharpLight opinion that the BEAMAX is substantially equivalent in terms of safety and effectiveness to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medic SharpLight Ltd.
% Quasar Quality Ltd.
Mr. Dan Laor
Managing Director
6 Sireni Street
Haifa 32972 Isreal

JAN 17 2007

Re: K063249
Trade/Device Name: BEAMAX
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: November 23, 2006
Received: December 1, 2006

Dear Mr. Laor:

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.

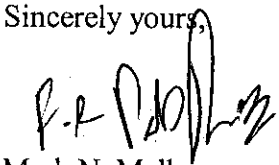
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (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): K063249

Device Name: BEAMAX

Indications For Use: The BEAMAX is intended for aesthetic and cosmetic use. The device is specifically indicated for removal of hair by using selective light energy.

Prescription Use: **YES** AND/OR Over-the-Counter Use: NO
(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 K063249