



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medicam, Inc.
% Mr. Philippe Amar
President
7900 Jean-Brillon
Montreal, Quebec, Canada H8N 2L5

SEP 29 2011

Re: K111350

Trade/Device Name: Medicam Evolus, Evostar, Evolight and
Evolase Pulsed Light Systems

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and
plastic surgery and in dermatology

Regulatory Class: Class II

Product Code: ONF

Dated: September 23, 2011

Received: September 26, 2011

Dear Mr. Amar:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

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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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



fs Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment IV

Indications for Use Statement

510(k) Number: K111350

Device Name: Medicam Evolux, Evostar, Evolight and Evolase Pulsed Light Systems

Indications for use:

The Medicam Evolux, Evostar and Evolight pulsed light systems (and included accessories) are indicated for use in surgical, aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue.

It is intended for use for:

- Removal of unwanted hair from all skin types (640nm to 1200nm);
- Treatment of benign pigmented lesions including dyschromia, hyper pigmentation, melasma, ephelides (freckles) (510nm to 1200nm);
- Removal of benign cutaneous vascular lesions including port wine stains, hemangiomas, rosacea, erythema, leg veins(485 nm to 1200nm); and
- Treatment of benign cutaneous lesions including warts, scars and striae (420nm to 1200nm).

The devices are intended for prescription use.

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Concurrence of CFRH Office of Device Evaluation (ODE)

M. R. P. Dale - for man
 (Division Sign-Off)
 Division of Surgical, Orthopedic,
 and Restorative Devices

Prescription Use X
(Per 21CFR801)

OR

Over-the-counter Use
510(k) Number K111350

Indications for use:

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The Medicam Evolase pulsed light system (and included accessories) is indicated for use in surgical, aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue.

It is intended for use for:

- Treatment of benign pigmented lesions including dyschromia, hyper pigmentation, melasma, ephelides (freckles) (1064nm to 1200nm); and
- Removal of benign cutaneous vascular lesions including port wine stains, hemangiomas, rosacea, erythema, leg veins (532nm to 1200nm).

The device is intended for prescription use.

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

Concurrence of CFRH Office of Device Evaluation (ODE)

Neil R. P. Ord for me
 (Division Sign-Off)
 Division of Surgical, Orthopedic,
 and Restorative Devices

Prescription Use X
(Per 21CFR801)

OR

Over-the-counter Use

510(k) Number K111350

510(k) Premarket Notification

Device Classification Name	<u>powered light based non-laser surgical instrument with thermal effect</u>
510(K) Number	K111350
Model	EVOLUX V4110, EVOLIGHT V4110, EVOSTAR V4110, EVOLASE V4110
Device Name	MEDICAM EVOLUX, EVOSTAR, EVOLIGHT AND EVOLASE PULSED LIGHT SYSTEM
Applicant	MEDICAM INC. 7900 jean-brillon montreal, quebec,
Contact	philippe amar
Regulation Number	<u>878.4810</u>
Classification Product Code	<u>ONF</u>
Date Received	05/13/2011
Decision Date	09/29/2011
Decision	substantially equivalent (SE)
Classification Advisory Committee	General & Plastic Surgery
Review Advisory Committee	General & Plastic Surgery
summary	<u>summary</u>
Type	Traditional
Reviewed by Third Party	No
Expedited Review	No
Combination Product	No