K111350

SEP 2 9 2011

Attachment 5

510(k) Summary

As required by 21 CFR 807.92(c)

Submitter	MEDICAM INC.
Address	7900 Jean-Brillon Montréal, QC Canada H8N 2L5
Phone	(514) 737-0404
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Contact Person	Philippe Amar President
Summary Date	May 5, 2011
Device Trade Name	Medicam Evolux, Evostar, Evolight and Evolase Pulsed Light Systems
Device common name	Laser Powered Surgical Instrument (and Accessories)
Classification Name	Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology (21 CFR 878.4810)
Legally Marketed Predicate Devices	➢ Profile BBL System (K032460) ➢ Quantum, Models SR, HR, DL (K020839)
System Description	Medicam Evolux, Evostar, Evolight and Evolase Pulsed Light Systems emit intense wide spectrum emission with wavelength of 420 - 1200 nm. It includes the following main components : ➢ A system console (including software and electronic control boards); ➢ A control and color touch screen; and

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	➢ Hand piece with cooling system.
Intended 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 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 devices are intended for prescription use.
Substantial Equivalence	The Medicam Evolux, Evostar, Evolight and Evolase Pulsed Light Systems shares the same indications for use, similar design and functional features and are therefore substantially equivalent to the above legally marketed predicate devices.
Safety and Effectiveness Information	The indications for use are based upon the indications for use from Predicate systems. Technologically, the Medicam Evolux, Evostar, Evolight

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	and Evolase Pulsed Light Systems are substantially equivalent to the listed predicate devices. Therefore, the risks and benefits for Medicam Evolux, Evostar, Evolight and Evolase Pulsed Light System are comparable to the predicate devices.
Conclusion	The Medicam Evolux, Evostar, Evolight and Evolase Pulsed Light Systems share similar indications for use, design features and similar functional features as the currently marketed predicate devices and therefore are substantially equivalent to them.

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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

Prescription Use X OR Over-the-counter Use
(Per 21CFR801)

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Indications for use: ***** Continued from Previous Page*****

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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

Prescription Use ___X___ OR Over-the-counter Use_____
(Per 21CFR801)

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(Rev. 2)

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.

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,

Eric I. Keith

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

Enclosure