DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Regulatory Insight, Incorporated
% Mr. Kevin Walls
5401 S. Cottonwood Court
Greenwood Village, Colorado 80121

JUL 13 2012

Re: K112505
Trade/Device Name: Etherea
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, ONF, ILY
Dated: March 27, 2012
Received: March 28, 2012

Dear Mr. Walls:

This letter corrects our substantially equivalent letter of April 6, 2012.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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,

FOR 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): K112505

Device Name: Etherea

Indications for Use:

Intense Pulsed Light (IPL-sq)

- ✓ Treatment mild to moderated inflammatory and pustular inflammatory acne vulgaris.
  (400nm and 640nm filters)
- ✓ The treatment of benign pigmented epidermal lesions including dyschromias, hyperpigmentation, melasma and ephelides (freckles).
  (540nm and 580nm filters)
- ✓ Lentigines, nevi, and café-au-lait macules.
  (540nm filter)
- ✓ The treatment of cutaneous lesions including warts, scars and striae.
  (scars and striae – 540nm, 580nm and 640 filters) (warts - 540nm and 580 filters)
- ✓ 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, and venous malformations.
  (540nm and 580nm filters)
- ✓ The removal of unwanted hair from all skin types, and to effect stable long-term, or permanent hair reduction.
  (580nm and 640nm filters)

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for MXM

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

510(k) Number K112505

Indications for Use

510(k) Number (if known): K112505

Device Name: Etherea

Indications for Use:

Infrared (Intense IR)

Topical heating for the purpose of elevating tissue's temperature for the temporary relief of minor muscle pain and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase of local circulation where applied, and the relaxation of muscles. In addition, may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

Laser Nd:Yag 1064nm (1064 LongPulse)

- ✓ Coagulation and hemostasis of vascular lesions and epidermal tissue, including the treatment of superficial and deep telangiectasias, reticular veins (0,1- 4 mm diameter) of the leg, rosacea, warts, venous lake, leg veins, poikiloderma of Civatte, angiomas, hemangiomas, and nevus;
- ✓ Non ablative treatment of facial wrinkles, scars and striae;
- ✓ The removal of unwanted hair from all skin types, and to effect stable long-term, or permanent hair reduction;
- ✓ Treatment of pseudofolliculitis barbae.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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510(k) Number K112505