OCT 1 1 2005

K052336

510(k) Summary

AMJET Distributing, LLC
SPECTRAQUATTRO PULSED LIGHT SYSTEM
510(k) Premarket Notification

Submitter:	AMJET Distributing, LLC
Address:	1025 Berkshire Road Minneapolis, MN 55437
Contact Person:	Stephen Trinter
Telephone:	612-812-1636
Facsimile:	651-702-4411
Date Prepared:	August 17, 2005
Device Trade Name:	SpectraQuattro Pulsed Light System
Common Name:	Pulsed Light System
Classification Name:	Instrument, Surgical, Powered, Laser 79-GEX, 21 CFR 878.4810
Legally Marketed Predicate Devices:	Radiancy, Inc. SkinStation™ Pulsed Light System (K030897, K032205, K051268), Palomar Estelux™ Pulsed Light System (K020453), CoolTouch, Inc. PRIMA Pulsed Light Therapy System (K041323).

Description of the SpectraQuattro Pulsed Light System:

The SpectraQuattro Pulsed Light System is intended to provide phototherapeutic light to the body. The SpectraQuattro is a compact, self-contained system that delivers a beam of pulsed light at wavelengths of 300nm to 1400nm, which can be optimized at various wavelength ranges and delivered to the treatment site. The system consists of a control console which houses the power supply, cooling system, handpiece that contains the light source, and footswitch.

Intended Use of the SpectraQuattro Pulsed Light System:

The SpectraQuattro Pulsed Light System is generally indicated to treat dermatological conditions. The SpectraQuattro is specifically indicated for the treatment of vascular lesions, rosacea, hemangiomas, leg veins, hair removal, pigmented lesions, lentigenes, and mild to moderate inflammatory and pustular inflammatory acne vulgaris.

Technological Characteristics And Substantial Equivalence:

The SpectraQuattro is a pulsed light system generally indicated for the treatment of dermatological conditions and the specific treatment of vascular lesions, rosacea, hemangiomas, leg veins, hair removal, pigmented lesions, lentigenes, and mild to moderate inflammatory and pustular inflammatory acne vulgaris. SpectraQuattro is substantially equivalent to the Cooltouch PRIMA, and has the same intended use, the same principles of operation and is technologically similar to the Cooltouch PRIMA, with only minor exceptions which do not raise issues in terms of performance, safety or effectiveness. Additionally, SpectraQuattro has the same intended use, similar indications for use, the same principles of operation

and similar technological characteristics as the Radiancy SkinStation and Palomar Estelux. SpectraQuattro is substantially equivalent to said predicate devices and minor differences between SpectraQuattro and these two systems does not raise any new issues in terms of performance, safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2005

Amjet Distribution, LLC
c/o Ned Devine
Responsible Third Pary Official
Intertek Testing Services NA, Inc.
70 Codman Hill Road
Boxborough, Massachusetts 01719

Re: K052336
Trade/Device Name: SpectraQuattro™ Pulsed Light System
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: September 23, 2005
Received: September 26, 2005

Dear Mr. Devine:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

for Mark N. Melkerson
Acting 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): K052336

Device Name: SpectraQuattro™ Pulsed Light System

Indications for Use:

The SpectraQuattro™ Pulsed Light System is generally indicated to treat dermatological conditions. The SpectraQuattro™ Pulsed Light System is specifically indicated for the treatment of vascular lesions, rosacea, hemangiomas, leg veins, hair removal, pigmented lesions, lentigenes, and mild to moderate inflammatory and pustular inflammatory acne vulgaris.

SpectraQuattro™ comes with a variety of light spectrum filters. These are indicated below, along with the respective indications for which they are recommended:

Light Spectrum Filter	Indications
410-1200	Mild to moderate inflammatory and pustular inflammatory acne vulgaris
530-1200	pigmented lesions
560-1200	lentigenes
585-1200	Vascular lesions,rosacea, hemangiomas, leg veins
640-1200	Hair removal

Prescription Use: ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 K052336