K 073066

Quantel Medical
510(k)
308 Dermatological Excimer System

510(k) Summary

(1) Submitter Information

Name: Quantel Medical

Address:

21 rue Newton - Zone du BREZET
Clermont-Ferrand 63039
France

DEC 2 6 2007

Telephone Number: 33-1-69-29-17-00

Contact Person:
Dr. George Myers (Official Correspondent)
Medsys Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604
Telephone 201-727-1703
Fax 201-727-1708

Date Prepared: October 1, 2007

(2) Name of Device

Trade Name: 308 Excimer Lamp Phototherapy system
Classification name: Ultraviolet Lamp for Dermatological Disorders

(3) Equivalent legally-marketed devices.

PhotoMedex VTRAC XL, K051428

(4) Description

The 308 is indicated for dermatological procedures for the treatment of psoriasis and vitiligo. The lamp is a xenon-chloride excimer lamp with a wavelength of 308 nanometers. Its output power is 800 mW ±10% for 2.48 in^2 (16 cm^2). It is computer controlled, and displays the treatment parameters.

(5) Intended Use

. The 308 system is intended to be used for the treatment of psoriasis and vitiligo.

(6) Performance Data

(a) Non-clinical tests

The 308 has been extensively validated, both the lamp itself and the software. It has been tested to ISO 60601-1 and ISO 60601-1-2. The lamp has been tested for output power and stability, and the software has been validated.

(b) Clinical tests

Clinical tests are not necessary, since the 308 uses the same technology as the predicate device.

(c) Conclusions

The 308 is equivalent in safety and efficacy to the legally-marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 6 2007

Quantel Medical, Inc.
% Medsys, Inc.
Mr. George Myers
377 Route 17
Hasbrouck Heights, New Jersey 07604

Re: K073066
Trade/Device Name: Model 308 Dermatological Excimer System
Regulatory Number: 21 CFR 878.4630
Regulatory Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: II
Product Code: FTC
Dated: October 25, 2007
Received: October 30, 2007

Dear Mr. Myers:

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,

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): K 073066

Device Name: Model 308 Dermatological Excimer System

Indications For Use:

The Quantel 308 Excimer System is intended to be used for the treatment of psoriasis and vitiligo.

Prescription Use ___X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brehm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073066