DEC 12 2008

Section 5

510(k) Summary

K081095

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.87 and 807.92. Summary preparation date 04-10-08 [21 CFR 807.92(a)(1)].

A. Contact Information [21 CFR 807.92(a)(1)]

Quantel USA

P O Box 8100

Bozeman, MT 59715

Tel: 406-586-0131

Fax: 406-586-2924

Contact person: Michael Johnson M.D.

B. Device Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade Name: ProLite III Intense Pulsed Light System

Device Common Name: Intense Pulsed Light (IPL)

Classification Name: Laser Instrument, Surgical Powered (per 21 CFR 878.4810)

Product Code: GEX

Panel: Dermatology and Plastic Surgery

Device Classification: Class II

C. Predicate Devices [21 CFR 807.92(a)(3)]

The *ProLite III* IPL device uses similar technology and has equivalent physical output characteristics as the following predicate devices:

ProLite, manufactured by Big Sky Laser Technologies, now Quantel USA (K021304)

Dermalux, manufactured by Palomar (K010618)

D. Device Description [21 CFR 807.92(a)(4)]

The *ProLite III* IPL is a device designed for dermatological use. It produces an intense light pulse within the wavelengths of 450 to 2000 nanometers, which is tailored to specific indications by a bandpass filter. The system is composed of a Tower which encloses the power supply and cooling system and a Handpiece which contains the flash lamp, filter and waveguide. The device is controlled by a touch-screen graphic user interface.

E. Device Specifications [21 CFR 807.92(a)(6)]

The *ProLite III* IPL outputs a flash with selectable pulse durations of 5 to 120 milliseconds with a shot fluence adjustable in the range of 5-30 J/cm^2. The maximal repetition rate is 1 shot per second. The photorejuvenation "PR" handpieces output the spectrum from 530 to 1100 nm, 550-1100 nm, or 580-1100 nm using a user-inaccessible bandpass filter. The hair removal "HR" handpieces output the spectrum from 630 to 990 nm, 630 to 1100 nm, or 650 to 1100 nm using a user inaccessible bandpass filter. The waveguide area is 6 cm^2 (1.5 x 4 cm). The waveguide is cooled by thermo-electric "Peltier" devices with the temperature setpoint adjustable from room temperature to 5°C.

F. Indications for Use [21 CFR 807.92(a)(5)]

The *ProLite III* ™ Pulsed Light System with the HR handpiece (containing a 630-1100 nm, 630-990 nm, or 750 – 1100 nm filter) is intended for the removal of unwanted hair in all Fitzpatrick skin types.

The *ProLite III* ™ Pulsed Light System with the PR handpiece (containing a 530-1100 nm, 550-1100 nm, or 580-1100 nm filter) is intended for the treatment of benign pigmented lesions and the removal of tattoos, the treatment of vascular lesions, and the treatment of shallow veins, telangiectasia, facial hemangiomas, and rosacea vascular lesions.

G. Conclusion [21 CFR 807.92(b)(3)]

Technologically, the *ProLite III* was found to be substantially equivalent to the currently cleared *ProLite* (K021303) and *Dermalux* (K021304). Thus, the risks and benefits for the *ProLite III* are comparable to the predicate devices.

The indications for use are exactly the same as the previously cleared pulsed light system, the *ProLite* (K021303).

We believe that there are no new questions of safety or efficacy raised by the introduction of the *ProLite III.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Quantel USA
% Michael Johnson, M.D.
601 Haggerty Lane
Bozeman, Montana 59715

DEC 12 2008

Re: K081095
Trade/Device Name: ProLite III
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: October 17, 2008
Received: October 20, 2008

Dear Dr. Johnson:

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

Section 4

Indications for Use

510(k) Number (if known): K081095

Device Name: ProLite III

Indications for Use:

The *ProLite III* ™ Pulsed Light System with the HR handpiece (containing a 630-1100 nm, 630-990 nm, or 750-1100 nm filter) is intended for the removal of unwanted hair in all Fitzpatrick skin types.

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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 mtm

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

510(k) Number K081095