PRIMARY TECHNOLOGY, LLC
813 S. Westshore Blvd.
Tampa, FL 33609
TEL: 813-288-0260 FAX: 813-288-0614

K022609 1/2

DEC 2 0 2002

REVISED – 11/04/02
510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness for the SpectraPulse® pulsed light device by Primary Technology is submitted in accordance with the requirements of Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(K) summary.

Applicant:	Primary Technology, LLC
Address:	813 S. Westshore Blvd. Tampa, FL 33609
Contact Person:	Stephen Almeida
Email:	salmeida@spectrapulse.com
Telephone:	TEL: 813-288-0260 FAX: 813-288-0614
Preparation Date:	August 5, 2002
Device Trade Name:	SpectraPulse®
Common Name:	Pulsed Light Device
Classification Name:	Light based surgical instrument for use in General and Plastic surgery and in Dermatology 21 CFR 878.48 Panel: 79
Legally marketed predicate Device:	Palomar Medical Technologies, Inc. EsteLux ™ K020453
System Description:	The SpectraPulse system is a light-based medical device designed for treatment of vascular lesions (fascial and leg) and benign pigmented lesions.
Intended use:	The SpectraPulse system is indicated for photocoagulation of dermatological vascular lesions, photothermolysis of blood vessels (facial and leg veins), benign pigmented

	lesions in skin types I-IV according to the Fitzpatrick scale.
Performance Data:	The differences in specifications of the Spectrapulse® and the predicate device do not result in different performance or raise new questions of safety or efficacy.
Conclusion:	Based on the foregoing, the SpectraPulse system is substantially equivalent to the legally-marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Stephen Almeida
President
Primary Technology, LLC
813 S. Westshore Boulevard
Tampa, Florida 33609

DEC 2 0 2002

Re: K022607
Trade/Device Name: SPECTRAPULSE®
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: November 6, 2002
Received: November 7, 2002

Dear Mr. Almeida:

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 (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

REVISED – 11/4/02

INDICATIONS FOR USE STATEMENT

510(k) Number: K022607

DEVICE NAME: SPECTRAPULSE®

INDICATIONS FOR USE:

The Spectrapulse® pulsed light system is intended for photothermolysis of blood vessels (facial and leg veins), photocoagulation of dermatological vascular lesions, and the treatment of benign pigmented lesions for skin types I – IV according to the Fitzpatrick scale.

(Please do not write below this line-Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K022607

Prescription use ✓ OR Over-the-Counter Use ____
(per 21 CFR 801.109)