

K971193

JUN 24 1997

EXHIBIT 1
Page 1 of 4

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K971193.

1. Submitter's Identification:

Polytec PI, Inc.
23 Midstate Drive, Suite 104
Auburn, MA 01501

Contact Person: Mr. Mark Boardman
Manager - Medical Laser Products

Date Summary Prepared: March 28, 1997

2. Name of the Device:

LaseAway Long Pulse and Q-Switched Ruby Laser System

3. Predicate Device Information:

1. LaseAway Q-Switched Ruby Laser System, K#942343, Polytec PI, Inc.
2. EpiLaser™ Normal Mode Ruby Laser, K#963947, Spectrum Medical Technologies
3. EpiTouch™ Ruby Laser System, K#962996, Sharplan

4. Device Description:

Using a wavelength of 694 nm., the LaseAway Long Pulse and Q-Switched Ruby Laser System consists of a Long Pulse and Q-Switched ruby laser together with an articulated delivery arm and focusing optics. The laser parameters are managed by an analog control unit which is coupled to the main system and calibration is facilitated by an energy detector in the front panel. The pulse operation is initiated by a footswitch and a visible helium neon laser to provide guidance for accurate beam delivery.

5. **Intended Use:**

The LaseAway Long Pulse and Q-Switched Ruby Laser System is intended to remove blue/black tattoos and benign dermal and epidermal pigmented lesions, and, to effect hair removal of patients with skin types 1:4 through selective targeting of melanin in hair follicles in dermatology and plastic surgery.

6. **Comparison to Predicate Devices:**

The LaseAway Long Pulse and Q-Switched Ruby Laser System is substantially equivalent in design and function to other ruby laser systems on the market, specifically:

1. The Polytec PI, Inc. LaseAway Q-Switched Ruby Laser System, K#942343;
2. The Spectrum Medical Technologies EpiLaser™ Normal Mode Ruby Laser, K#963947; and
3. The Sharplan EpiTouch™ Ruby Laser System, K#962446.

The LaseAway Long Pulse and Q-Switched Ruby Laser System device is a Long Pulse and Q-Switched Ruby Laser and both the EpiLaser™ and EpiTouch devices are Non-Q-Switched (Long Pulse Ruby). Exhibit #2 outlines all parameter differences; the intended use of the Sharplan Ruby Laser System is limited to use in dermatology for the removal of unwanted dark body hair.

A comparative description of the EpiTouch™ and EpiLaser™ devices to the LaseAway Long Pulse and Q-Switched Ruby Laser System is outlined below:

- The EpiLaser™ (Spectrum Medical Technologies):

The EpiLaser™ is a non-Q-Switched, long pulse, flashlamp pumped ruby laser with a wavelength of 694 nanometers. EpiLaser has an energy output of 25 joules allowing it to have a maximum fluences at 9 mm of 40 joules/cm² with a repetition rate of 0.5 Hz. The EpiLaser™ has a peak power output of 8.3 kilowatts with a pulse duration of 3 milliseconds. The laser beam is delivered to the treatment site through an articulated arm and a focusing handpiece where patient contact is made

with a water cooled sapphire tip. The power supply needed for the system is 220 volts AC plus or minus 7 percent with a 30 amp current draw and an alternating current cycle 50 or 60 hertz. The exterior dimensions of the system are 40 inches tall by 24 inches wide by 44 inches deep and an operation weight of 790 pounds.

The major differences between the EpiLaser™ and LaseAway are the pulse width which is longer in the EpiLaser™ by almost 2 milliseconds, the energy delivery spot size which is almost double in the EpiLaser and the peak power which is higher in the EpiLaser by almost 3 kilowatts. The minor differences are in the cooling handpiece, the exterior dimensions, the operating weight and the current draw needed to run the systems.

- The EpiTouch™ (Sharplan):

The EpiTouch™ is a Q-Switched, long pulse, flashlamp pumped ruby laser with a wavelength of 694 nanometers. EpiTouch has an energy output of 5 joules allowing it to have a maximum fluences at 4 mm of 40 joules/cm² with a repetition rate of 1.2 Hz. The EpiLaser™ has a peak power output of 5.5 kilowatts with a pulse duration of 0.9 milliseconds. The laser beam is delivered to the treatment site through an articulated arm and a focusing handpiece where patient contact is made with an anodized aluminum. The power supply needed for the system is 220 volts AC plus or minus 10 percent with a 10 amp current draw and an alternating current cycle 50 or 60 hertz. The exterior dimensions of the system are 45 inches tall by 29 inches wide by 33 inches deep and an operating weight of 440 pounds.

The only difference between the EpiTouch™ and the LaseAway Long Pulse and Q-Switched Ruby Laser System is the exterior size. The LaseAway Long Pulse and Q-Switched Ruby Laser System is 24 inches tall by 47 inches wide by 21 inches deep.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing information demonstrating safety and effectiveness of the LaseAway Long Pulse and Q-Switched Ruby Laser System, in

the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlined Electrical, Mechanical and Environmental Performance Requirements.

Testing was conducted on the LaseAway Long Pulse and Q-Switched Ruby Laser System device per IEC-601-1 (electrical isolation) and IEC 601-1-2 (EMC testing).

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards.

8. Discussion of Clinical Tests Performed:

A clinical study was conducted using the device to support the claim for the treatment of hirsutism. A description of the protocol, including patient population, the results of the study and a summary of the data and analysis of the data to demonstrate the equivalence of the LaseAway Long Pulse and Q-Switched Ruby Laser System to legally marketed devices was supplied to the FDA. The aforementioned clinical data was obtained under IRB with written consent from patients. Included is a statement from the IRB that our protocol contents were considered under a non-significant risk device. The clinical data was obtained in accordance with 21 CFR Parts 50 and 56.

9. Conclusions:

The LaseAway Long Pulse and Q-Switched Ruby Laser System has the same intended use as the Spectrum Medical Technologies EpiLaser™ device and is similar in design and technology as this device as well as the Sharplan EpiTouch™ device: As our "Comparison to Predicate Devices" Section 6 outlines, as well as our clinical data, the LaseAway Long Pulse and Q-Switched Ruby Laser System raises no new questions of safety or effectiveness. Thus, when compared to the predicate devices, the LaseAway Long Pulse and Q-Switched Ruby Laser System did not incorporate any significant changes in intended use, method of operations, material or design that could affect safety or effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Susan D. Goldstein-Falk
Official Correspondent
Polytec PI, Inc.
23 Midstate Drive, Suite 212
Auburn, Massachusetts 01501

JUN 24 1997

Re: K971193
Trade Name: LaseAway Long Pulse and Q-Switched Ruby Laser System
Regulatory Class: II
Product Code: GEX
Dated: March 28, 1997
Received: April 1, 1997

Dear Ms. Goldstein-Falk:

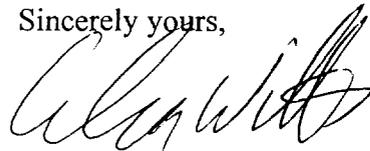
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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

Enclosure

510(k) Number (if known): K971193

Device Name: LaseAway Long Pulse and Q-Switched Ruby Laser System

Indications For Use:

The LaseAway Long Pulse and Q-Switched Ruby Laser System is intended to remove blue/black tattoos and benign dermal and epidermal pigmented lesions; and, to effect hair removal of patients with skin types 1-4 through selective targeting of melanin in hair follicles in dermatology and plastic surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Alan Wilk

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K 971193

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use