

MAR 27 2008
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K073111

510(k) Summary

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For the Rhytec, Inc. Portrait® PSR³

General Information

Submitter: Rhytec, Inc.
130 Turner Street
Building Two
Waltham, MA 02453

Contact Person Robert Zoletti
Rhytec, Inc.
130 Turner Street
Building Two
Waltham, MA 02543
Telephone: 781-419-9482
Email: rzoletti@rhytec.com

Summary Preparation Date: March 24, 2008

Names

Trade Name: Portrait® PSR³ System
Common Name: (None)
Classification Name: Electrosurgical cutting and coagulation device
Product Code: GEI

Legally Market Predicate Devices

K071786 Portrait® PSR³
K963339 Coherent UltraPulse
K030453 CoolTouch ND:YAG
K053047 Fraxel ISR Laser System

Device Description

The Portrait® PSR³ is an electro-surgical device for use in dermatological applications. The effect of the device is achieved by heating the outer layer of the skin so that part or all of the epidermis becomes non-viable and there is controlled damage to the underlying dermis. Similar biological changes are produced as with established laser-based and RF-based dermatological surgical and skin resurfacing technologies.

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The system includes:

- Portrait® PSR³ Generator-a mobile unit powered from 110/230 VAC standard wall socket comprising a trolley and lift-out section referred to as a "generator section". Treatment parameters are displayed on the control panel.
- Footswitch-a single pedal unit for activation
- Handpiece and Cable Assembly-this carries RF power and Nitrogen gas to the Nozzle.
- Treatment Pack comprising a disposable Nozzle that is connected to the Handpiece and an electronic "treatment pack key" that is used by the generator to ensure the Nozzle is not used beyond its validated operational life. The instrument does not touch the skin during treatment.
- Nitrogen Gas Cylinder - the gas is provided in a cylinder housed in the generator enclosure. Refill cylinders containing the required purity of Nitrogen are obtained by the user from a commercial gas product supplier.

Indications for Use Statement

The Portrait® PSR³ System is intended for treatment of the following dermatological conditions:

- Treatment of wrinkles and rhytides
- Superficial skin lesions
- Actinic Keratosis
- Viral Papillomata
- Seborrhoeic Keratosis
- Acne Scars

Technological Characteristics

The technology involved in the Portrait® PSR³ System is not changed from previous Portrait® PSR³ submissions.

UHF energy from the generator converts Nitrogen gas into plasma within the Handpiece. The plasma emerges from the Nozzle at the distal end of the Handpiece and is directed onto the skin to be treated. Rapid heating of the skin occurs as the excited gas gives up energy to the skin. Through the combination within the Handpiece of precisely controlled energy and Nitrogen gas, individual plasma pulses are produced that will give predictable tissue effects.

The Portrait® PSR³ uses Nitrogen plasma as compared to laser light used by UltraPulse, CoolTouch ND:YAG and Fraxel ISR Laser System.

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Substantial Equivalence Comparison

Portrait® PSR³ utilizes the same technology as previously cleared for Portrait® PSR³. There have been no changes to the device design. The substantial equivalence of this device is supported by the prior approval of this device and the clinical data submitted. Other devices used to treat acne scars include the 1320-nmNd:YAG (K030453), Fraxel SR 1500 (K070284) and CO2 Laser (K963339).

Clinical and Non-Clinical Data

Clinical studies demonstrated that the Portrait® PSR³ is capable of producing tissue effects similar to that seen with carbon dioxide laser treatment. Clinical studies to support clinical performance of the Portrait® PSR³ to improve acne scarring were conducted as Non-Significant Risk studies and undertaken in compliance with the Code of Federal Regulations, as specified in 21 CFR 812. These studies conclude that the Portrait® PSR³ is safe and effective for treating acne scars.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Rhytec Incorporated
% Mr. Robert Zoletti
Director RA
130 Turner Street
Building Two
Waltham, Massachusetts 02543

MAR 27 2008

Re: K073111
Trade/Device Name: Portrait® PSR³ System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: February 29, 2008
Received: March 04, 2008

Dear Mr. Zoletti:

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.

Page 2 – Mr. Robert Zoletti

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

Indication for Use

510(k) Number: K073111

Device Name: *Portrait*[®] *PSR*³

Indications for use:

The *Portrait*[®] *PSR*³ is intended for treatment of the following dermatological conditions:

1. Treatment of wrinkles and rhytides
2. Superficial skin lesions
3. Actinic keratosis
4. Viral papillomata
5. Seborrhoeic keratosis
6. Acne Scars

Prescription Use X

And/Or

Over the Counter Use

(21 CFR Part 801 Subpart D)
Subpart C)


(21 CFR Part 801

(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 K073111