K072394

Pg. 1 of 1

510(k) Summary

SEP 12 2007

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:	August 3, 2007

Names

Trade Name:	Portrait® PSR³ System
Classification Name:	Electrosurgical cutting and coagulation device Product Code: GEI

Legally Market Predicate Devices

K071786 Portrait® PSR³

Device Description

The Rhytec, Inc. Portrait® PSR³ System is an electro-surgical device for use in dermatological applications. 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 detachable Nozzle Stand-off (distance gauge) assists the user in maintaining the proper distance between the Nozzle and the skin.

The modification is a reusable/disposable Standoff distance gauge accessory to the Portrait® PSR^3 system.

Indications for Use Statement

The Portrait® PSR^3 System is intended for treatment of the following dermatological conditions:

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

The indications are unchanged from K071886.

Technological Characteristics

The Stand-off is provided in two sizes: 5 mm and 25 mm. Materials include Ultem 1000 and Accura® DuraForm™ PA Polyamide (nylon). It is used in place of the non-contacting LED targeting ring to establish the distance between the Nozzle and the patient's skin.

Substantial Equivalence Comparison

The Stand-off is equivalent to the current non-contacting optical (LED) targeting system. It also provides the equivalent function of the distance gauges provided with the Candela Gentle YAG Laser System.

Clinical and Non-Clinical Data

The Stand-off was bench tested to assure usability and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Rhytec, Inc.
% Mr. Robert Zoletti
Director, Regulatory Affairs
and Quality
130 Turner Street
Building Two
Waltham, Massachusetts 02543

SEP 12 2007

Re: K072394
Trade/Device Name: Rhytec, Inc. Portrait® PSR^3
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 24, 2007
Received: August 27, 2007

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.

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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

K072394

Indications for Use

510(k) Number (if known): _____

Device Name: __ Rhytec, Inc. Portrait®
PSR³

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

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

Indications for Use are unchanged from K071786

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)

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

510(k) Number K072394