K093100

510(k) Summary
(per 21 CFR 807.92(c))

1. Applicant

Shenzhen Comfort Technology Co. Ltd.
No. 3 Building North Nanling Road
Xiner Industrial Zone
Shenzhen, China

NOV 24 2009

Mr. Jack Zhou, General Manager
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Date Prepared: August 5, 2009

2. Device Name

Device Name:	Revlon RVSP3501 (Type SPB3752EA) Spa MoistureStay Paraffin Bath
Regulation Description:	Paraffin bath
Regulation Number:	890.5110
Product Code:	IMC
Device Class:	II
Review Panel:	Physical Medicine

3. Predicate Devices

The Revlon RVSP3501 (Type SPB3752EA) Spa MoistureStay Paraffin Bath is substantially equivalent to the following device:

510(k) Number	Device	Applicant
K022626	Revlon RVS1212 (MoistureStay) Luxury Paraffin Spa	Raymond Industrial, Ltd.

4. Indications for Use

The Revlon RVSP3501 Spa MoistureStay Paraffin Bath is:

- Useful in symptomatic relief of pain caused by arthritis, bursitis, and chronic joint inflammation.
- Relaxes muscles, relieves stiffness and muscle spasm
- Stimulates circulation and for other conditions where heat is indicated.

5. Description of the Device

The Revlon RVSP3501 (Type SPB3752EA) Spa MoistureStay Paraffin Bath is an 80 Watt paraffin bath unit, with a thermostat that varies the heat from High to Keep Warm. There are two LEDs, a red LED for the heater, and a green LED to indicate the power. The unit is provided with 3lbs of paraffin wax, a plastic mat when dipping the hands or feet, glove liners, and a pair of mitts.

6. Summary of the Technical Characteristics

- Safety Testing

The Revlon RVSP3501 Spa MoistureStay Paraffin Bath was evaluated and found to comply with the applicable requirements of the following standards:

- UL1431 Standard for Personal Hygiene and Health Care Appliances, 2nd Edition, November 22, 1996, revised March 26, 2007
- Canadian Standard for Household Cooking and Liquid-Heating Appliances, CAN/CSA C22.2 No. 64-M91 (R2003)

- Performance Testing

The Revlon RVSP3501 Spa MoistureStay Paraffin Bath - Type SPB3752EA was tested alongside the Revlon Model RVS1212 Luxury Paraffin Spa (K022626). The major difference between the two units was the time required to melt the wax, as was expected, because of the significant difference in power consumption

7. Safety and Effectiveness

The Revlon RVSP3501 Spa MoistureStay Paraffin Bath has been shown to be as safe and as effective as the predicate device listed in this 510(k) submission; that is, both the Revlon RVSP3501 Spa MoistureStay Paraffin Bath and the Revlon RVS1212 (MoistureStay) Luxury Paraffin Spa have the same indications for use and are similar in both design and function. Any differences in technological characteristics between the Revlon RVSP3501 Spa MoistureStay Paraffin Bath and the predicate device do not raise issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

NOV 2 4 2009

Shenzhen Comfort Technology Co., Ltd.
% Intertek Testing Services NA, Inc.
Mr. Daniel W. Lehtonen
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K093100
Trade/Device Name: Revlon RVSP3501 (Type SPB3752EA) Spa MoistureStay Paraffin Bath
Regulation Number: 21 CFR 890.5110
Regulation Name: Paraffin bath.
Regulatory Class: Class II
Product Code: IMC
Dated: November 9, 2009
Received: November 10, 2009

Dear Mr. Lehtonen:

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.

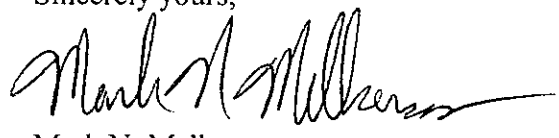
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Revlon RVSP3501 (Type SPB3752EA) Spa MoistureStay Paraffin Bath

Indications for Use:

The Revlon RVSP3501 (Type SPB3752EA) Spa MoistureStay Paraffin Bath is:

- Useful in symptomatic relief of pain caused by arthritis, bursitis, and chronic joint inflammation.
- Relaxes muscles, relieves stiffness and muscle spasm
- Stimulates circulation and for other conditions where heat is indicated.

Prescription Use (Part 21 CFR 801 Subpart D)		AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	X

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093100