REMINGTON

REMINGTON PRODUCTS COMPANY L.L.C.

DEC 0 3 2001

K013328

510(k) Summary

Tim Simmone
Vice President and
Chief Technical Officer

Preparation Date: October 5, 2001

Contact Person: Tim Simmone
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Remington Products Company, L.L.C.
60 Main Street
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Proprietary Name: Remington® Paraffin Spa (Models HS-250 and PFS-600)
Common/Usual Name: Paraffin Bath
Classification Name: Paraffin Bath (per 21 C.F.R. § 890.5110)

Classification: Class II

Description:

The product covered by this 510(k) summary is a heated paraffin wax spa intended for home use. This product consists of a plastic enclosure, aluminum bucket and an internal heating assembly. The paraffin wax temperature is controlled by a variable electronic heat control with timing circuit. Temperature settings (low, medium, and high) and timing controls are displayed on a liquid crystal display. The product consumes 200 watts when plugged into a standard household electrical outlet supply of 120 Vac, 60 Hertz. The product comes in two different sizes.

Intended Use:

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

Substantial Equivalence Claim:

The Remington Paraffin Spa® is substantially equivalent to the following legally marketed predicate device: ParaSpa™ Paraffin Bath by Homedics, Inc. (K001860).

Substantial equivalence is claimed because the Remington Paraffin Spa® and the HoMedics ParaSpa™ Paraffin Bath have the same intended use and very similar principles of operation and technological characteristics. Moreover, none of the minor technological differences between the two products raises any new questions of safety or effectiveness.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 3 2001

Remington Products Company, L.L.C.
c/o Ms. Pamela J. Furman
Olsson, Frank and Weeda, P.C.
1400 Sixteenth Street, NW
Suite 400
Washington, D.C. 20036-2220

Re: K013328
Trade/Device Name: Remington® Paraffin Spa (Models HS-250) and PFS-600)
Regulation Number: 890.5110
Regulation Name: Paraffin Bath
Regulatory Class: Class II
Product Code: IMC
Dated: October 5, 2001
Received: October 5, 2001

Dear Ms. Furman:

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

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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,

for Mark N. Melkerson

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

Enclosure

K013328

U.S. Food and Drug Administration – Center for Devices and Radiological Health

510(k) Number (if known): (Not yet assigned)

Device Name: Remington® Paraffin Spa

Indications for Use:

- 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhem

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

510(k) Number K013328

(Optional Format 3-10-98)