510(k) Summary
as required by 807.92

K071596

1. Company Identification

NIHON SEIMITSU SOKKI CO., LTD. (Nissei)
2508-13 Nakago, Shibukawa, Gunma 377-0293 Japan
Tel: +81-279-20-2311
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FEB 15

2. Official Correspondent

Hideki Tomaru (Mr.)
Assistant Manager of International Sales Div.

3. Date of Submission

June 11, 2007

4. Trade/Proprietary Name

Portable Air Massager putifino AM-7

5. Classification Number

Class II, IRP, 21 CFR 890.5650 – Powered inflatable tube massager

6. Predicate Device

Manufacturer	:	Salton, Inc
Trade Name	:	Relaxor Perfect Touch Air Massaging System
510(k) No.	:	K050697, Cleared on April 10, 2003

7. Description of Device

Portable Air Massager putifino AM-7 is a powered inflatable tube massager, which stimulates kneading and stroking of tissues with the hands by pressurizing and depressurizing the massaging garment (cuff) wrapped around the calf. The cotton and velour massaging cuff with inflatable bladder inside is assembled to the controller to facilitate the device's compactness and portability. The device is applicable to calves whose circumferences are between 8.7 to 17.7 inches (22 to 45 cm). With the included attachable extension hook, the applicable range extends to 19.7 inches (50 cm).

The device owns three modes of massage pattern and three levels of massage intensity, which are controlled by the microprocessor. Operation of the mode button on the controller during massaging will switch the massage patterns. In MODE 1, massage is given by repetition of pressurization and depressurization of the cuff, where pressurization is set to one pressure level. In MODE 2, massage pattern of MODE 1 is repeated at two pressure levels. In MODE 3, which is intended to temporary increase blood circulation, approximately 10 minutes of massage at low pressure level and approximately 20 minutes of rest are repeated. In MODE 1 and 2, operation of the pressure button on the controller will switch the massage intensities: weak, moderate and hard. The user of the device can confirm both massage mode and level with the illuminated indicator on the controller.

8. Indication for use

The Portable Air Massager putifino AM-7 is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Portable Air Massager putifino AM-7 simulates kneading and stroking of tissues by using an inflatable garment (Cuff).

9. Technological characteristics of the subject device

The device, powered with two AA alkaline batteries, achieves its intended use by inflating and deflating the bladder inside the massaging garment with the air pump and the electric control valve. The microprocessor controls inflation and deflation of the bladder to conduct massage in three different modes and to provide massage at different intensities.

The comparison table of the technological characteristics of the predicate device and the subject device is attached as Appendix 1.

The predicate and subject devices share the same operational principal, that is, to provide massage by inflating and deflating massage garment wrapped around a part of the body. The differences between the devices arise in product features due to mechanical structures that the subject device is designed to be portable. The product features of the predicate device to change massage garments as mentioned above and to specify massage areas, which is enabled with the garment with separated chambers, are not equipped with the subject device. The other difference due to the structure is that the devices are operated with different power sources; the predicate is powered by AC adapter and the subject device by batteries. Although the product features are not identical, these characteristic differences should not affect the substantial equivalence of the subject device to the predicate device.

10. Conclusion

The Portable Air Massager putifino AM-7 is substantially equivalent to Salton, Inc., Relaxor Perfect Touch Air Massaging System K050697.

Appendix 1: Comparison Table with Predicate Device

<table>
<tr><th>SUBJECT DEVICE:AM-7</th><th>PREDICATE DEVICE:K030437</th></tr>
<tr><td>INDICATION FOR USE

The Portable Air Massager putifino AM-7 is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Portable Air Massager putifino AM-7 simulates kneading and stroking of tissues by using an inflatable garment (Cuff).</td><td>INDICATION FOR USE

The Perfect Touch Air Massaging System is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Perfect Touch simulates kneading and stroking of tissues by using an inflatable garment.</td></tr>
<tr><td>INDICATIONS

Power
Pressure
Mode</td><td>INDICATIONS

Speed
Intensity
Press Zone</td></tr>
<tr><td>MODE OF COMPRESSION

Intermittent</td><td>MODE OF COMPRESSION

Intermittent</td></tr>
<tr><td>MASSAGE OPERATION

Massage level:3 (Weak, Moderate, Strong)
Massage pattern:3(Mode1, Mode2, Mode3)
Mode3 is Blood circulation improvement mode</td><td>MASSAGE OPERATION

Speed:10 Speed settings
Massage level:6 Levels
Zone:16Zone</td></tr>
<tr><td>MASSAGE TIME

Mode1: 10 minutes
Mode2: 10 minutes
Mode3: Approximately 10 minutes of massage and approximately 20 minutes of rest are alternately repeated.</td><td>MASSAGE TIME

15 minutes</td></tr>
<tr><td>MASSAGE PRESSURE

Massage Pattern is Mode1:
Weak:9.3kPa (70mmHg)
Moderate:13.3kPa (100mmHg)
Strong:17.3kPa (130mmHg)

Massage Pattern is Mode2:
Weak:9.3kPa (70mmHg),10.7kPa(80mmHg)
Moderate:13.3kPa(100mmHg),14.7kPa(110mm Hg)
Strong:17.3kPa(130mmHg),18.7kPa(140mmHg)

Blood stream improvement with Mode3:
Pressure is keep at 6.0kPa (45mmHg)</td><td>MASSAGE PRESSURE

<table><tr><td>Intensity Settings</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td></tr><tr><td>Garment Air Pressure</td><td>80 (mm Hg)</td><td>104 (mm Hg)</td><td>128 (mm Hg)</td><td>152 (mm Hg)</td><td>176 (mm Hg)</td><td>200 (mm Hg)</td></tr></table></td></tr>
<tr><td>MASSAGE PART

Calves</td><td>MASSAGE PART

Leg & Foot, Feet, Arm,
Neck & Shoulders, Lower Back, Hands</td></tr>
<tr><td>PRESSURE RANGE

0-200mmHg</td><td>PRESSURE RANGE

0-250mmHg</td></tr>
</table>

SUBJECT DEVICE:AM-7	PREDICATE DEVICE:K030437
NUNBER OF CHAMBERS 1	***NUNBER OF CHAMBERS*** 1 to 12, Varies with Garments
MATERIAL Operation Unit: ABS Massage Garment: Surface: Cotton / Polyester / Nylon Back: Velour	***MATERIAL*** Operation Unit: ABS Massage Garment: TPU Nylon with TPU Backing 190X70 with TPU Backing
Pressure control Microprocessor and Pressure Sensor	***Pressure control*** Microprocessor
Inflation Pressurization pump	***Inflation*** Pressurization pump
Deflation Electronic control exhaust valve	***Deflation*** exhaust valve
POWER SOURCE 2×1.5-Volt"AA" Alkali battery Consumption 2W	***POWER SOURCE*** Main body:120V 60Hz Consumption 26W AC Adapter:120V 60Hz Consumption 36W

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 15 2008

Nihon Seimitsu Sokki Co., Ltd.
% Cosmos Corporation
Mr. Koji Kubo
Manager
3F, 2-17-6 Akebono-cho
Tachikawa-shi
Tokyo 190-0012 Japan

Re: K071596
Trade Name: Portable Air Massager putifino AM-7
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered inflatable tube massager.
Regulatory Class: Class II
Product Code: IRP
Dated: January 12, 2008
Received: January 16, 2008

Dear Mr. Kubo:

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

Mr. Koji Kubo

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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

Indications for Use

510(k) Number (if known): K071596

Device Name : Portable Air Massager putifino AM-7

Indications for Use:

The Portable Air Massager putifino AM-7 is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Portable Air Massager putifino AM-7 simulates kneading and stroking of tissues by using an inflatable garment (Cuff).

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 K071596