K990145

JAN 18 2000

510 (k) Summary

Applicant's Name: LPG USA

Applicant's Address: 3101 North Federal Highway (Suite (301)
Fort Lauderdale, FL 33306

Contact Person: Walter L. Wasserman

Phone Number/contact person: (954)568-5005
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Address of manufacturing site: LPG Systems
Technoparc de la Plaine
30 Rue du Docteur Abel
BP 35-26902 Valence Cedex 9, France

Date Summary Prepared: January 18, 2000

This summary includes sections 2 through 8.

2. Device Name

- Therapeutic Massager (21 CFR 890.5660)
- Proprietary names – LPG Therapeutic Massager - Models - ES1
- Therapeutic Massager/Vibrator (21 CFR 890.5660 and 890.5975)
- Proprietary names - LPG Therapeutic Massager/ Vibrator – Models – Cellu M6; ES/M60; S6; and LPG Equine

3. Establishment registration number

1062948

4. Classification of device
- Class I
- Product codes – 89 ISA and 89 IRO
- Panel - Physical medicine

5. Performance standards

There are no performance standards established under section 514

6. Labeling

6.1

Indications for use

- Relieves minor muscle aches and pains
- Relieve muscle spasm
- Temporary improvement in local circulation
- Temporarily reduces the appearance of cellulite
- Relieves minor muscle aches and pains, relieves muscle spasm and temporarily improves local circulation during Burn rehabilitation

Contraindications

- Known sensitivity to the device
- Do not treat over open wounds
- Skin cancer in the treated area
- Do not treat HIV positive patients

Caution

Federal law restricts thus device for sale to or use under the order of a licensed physician

Precautions;

When treating patients for burn rehabilitation care should be taken to carefully follow the instruction manual and not to exceed suction levels that would be obviously uncomfortable for the patient.

6.2

510(k) Number K99045
Device Name: LPG Therapeutic Massager/Vibrator

Intended uses

- Relieves minor muscle aches and pains
- Relieve muscle spasm
- Temporarily Improve local circulation
- Temporarily reduces the appearance of cellulite
- Relieves minor muscle aches and pains, relieves muscle spasm and improves local circulation during Burn rehabilitation

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use _____ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

7. Substantial equivalence comparison

This product is substantially equivalent to a product already on the market LPG Therapeutic Massager (21 CFR 890.5660). The LPG technique involves a mobilization of the tissue accomplished with the LPG devices. All models with the exception of the ES1 and LPG Equine have both continuous and cyclic or pulsating modes of action. This pulsating function is equivalent to Therapeutic Vibrators (21 CFR 890.5975). And as such Substantial Equivalence is also claimed to the following legally marketed devices, which are also Class I.

- G5-GK1 - K850851
- VIBRATOUCH™ II K912383

Table of Comparison

Device	Indications	Design	Specifications
LPG Massager/Vibrator	Minor muscle pain Relieve muscle spasm; Temp. improvement in appearance of cellulite; Temp. increase of local circulation; Burn Rehab.	5 models 5 applicators 12 treatment heads 3 motorized heads	Ground current Leakage <50 micamp.
G5-GK1 Vibrator	Minor muscle pain	17 applicators 3 models hand held	12'x3'x3' - 3.8 lbs.; 0.25HP; 110V, 60 cycle <75 micamp. ground current leakage
VIBRATOUCH II	Minor muscle pain	2 speeds; Battery Power	not specified

Our objective is not to substantiate new claims but to prove that the exempt claims are appropriate for the burn victim and that the product is safe and effective for its general uses when used in burn rehabilitation.

8.

The LPG Technique:

The LPG technique involves mobilization of tissue accomplished with the LPG devices.

LPG stands for Louis Paul Guitay inventor of these therapeutic massagers.

LPG after a car accident that had left scars on his body was receiving treatments from a physical therapist using a tissue mobilization technique called Skin Fold Rolling. After a number of treatments, LPG noticed a difference in the Skin Fold Technique due to the practitioner performing the maneuvers or the time of the treatment. LPG had the idea to make the technique more consistent and replicable using vacuum power to lift the skin and make a fold that is mobilized by two motorized rollers.

The LPG devices:

Based on similar concepts, the LPG devices are intended for practitioners who work in specific fields but all are substantially equivalent devices:

- ES1 for Endermologie
- Cellu M6 for Endermologie and therapeutic applications
- S6 sport for sport applications, before, after exercise and rehabilitation after injuries
- ES/M60 for therapeutic applications and cosmetic applications on the face or on small area
- LPG Equine for animal treatment.

These devices are substantially equivalent to the ES1 therapeutic massager because the mode of operation and operating parameters and specifications are basically the same.

Each LPG device comprises a main console housing a vacuum pump and a computerized regulation system.

All of them contain treatment heads (from 5 to 12), that are designed to accommodate all parts of the body. ES1, Cellu M6, S6, LPG Equine devices have a main motorized head, the other device contain auxiliary heads (non-motorized) only. The equine device head is the largest in order to be able to be applied on the horse's body surface.

The suction power of all these machines range from 50mBar to 500mBar which is represented by a scale from 1 to 10; for a specific machine and application, the suction power must be cyclically interrupted to provide vibration to the skin which is another stimulation for the tissues.

The motorized head:

This patented head (*number 4,729,368 US*) contains more than 200 individual parts and contains two motorized rollers that move together and apart, at each end of the suction chamber. The two rollers are mobilized in rotation and in sliding back and forth. They provide, to the

head, the capability of creating a fold of skin and subcutaneous fat with a very efficient contact, which allows better mobilization. This is also enhanced by specific maneuvers.

To visualize the reaction of tissue in-vivo, some endoscopic views were recorded within the main head.

The auxiliary heads:

In addition to the main head, a set of auxiliary heads can be used with two non-motorized rollers on smaller parts of the body, particularly the face, the limbs, the neck, and all the specific area, which need treatment. These heads are called regarding the size of the rollers: 15, 30, 44 millimeters; the ES/M60 device contains a larger head with specific ergonomic features (i.e. handle on the top of the head) but the same design. Recently, LPG had added small springs at each end of the rollers to provide lateral mobilization of them during the treatment.

Rhythmicity or cyclic pulsation and mobilization:

For a specific machine and application (Cellu M6, S6, M60, and LPG Equine), the suction power is cyclically interrupted to provide vibration to the skin fold between the two rollers, which is another form of stimulation for tissues. Added to the device for the comfort of the patient, the cyclic suction power, according to scientific literature, provides additional effects to the tissue. Because of that, the therapeutic massager that includes vibration could be described as a form of therapeutic vibrator as well.

This cyclic pulsation feature is modulated by two variables:

- **Cycle rate**

The cycle rate regulates the proportion of time devoted to suction and rest. It is a ratio, the cycle rate ranges from 1 to 9, 1 for 10% suction versus 90% rest, 9 for 90% suction versus 10% rest, 5 for 50% suction versus 50% rest.

- **Frequency**

The frequency is the number of repetitions of one cycle per second. The frequency range from 0.41 to 19.23 Hz; these numbers appears on the screen as 0.0 for 0.41 Hz to 199 for 19.23 Hz.

In order to apply to the skin fold effective vibration, it is necessary to choose an adjustment with high frequency and low cycle rate or low frequency and high cycle rate. If the chosen adjustment is high frequency and high cycle rate, the skin fold is constantly lifted and the action is equivalent to the constant suction. If the chosen adjustment is low cycle rate and low frequency, the skin fold is mostly relaxed and therefore there will be less or no effectiveness.

This cyclic pulsation should not be considered as a single event but rather as repetitive stimulation that could produce harmonics (additional modes of stimulation). Thus the specific adjustments of the machine are less significant than it appears because of the harmonic summation.

The literature contains many citations showing the effectiveness of vibration of various frequencies; (i.e. has been shown on microcirculation, on pain and on muscle spasm).

LPG has investigated this area in one studies:
Doctor Gavroy compared treatment on burn victim with LPG and rhythmicity and LPG without rhythmicity.

History of the LPG Technique:

A number of French medical doctors advised Louis Paul Guitay about using the device to treat low back pain, a condition very frequently associated with some types of change in the skin and subcutaneous fat. This is called secondary cellulitis on the back or around the pelvic bone (iliac crest). They also recommended treating neck ache with huge fatty localization around C7 (which is called buffalo hump).

Therapist successfully using the CelluM6 device on female patients suffering low back pain, also noticed that their patients were showing an improvement in the appearance of their cellulite or commonly called orange peel skin.

Results on the appearance of cellulite were so significant that LPG decided to market the product for this effect. The device was then sold for two applications (cosmetic and therapeutic).

When LPG decided to sale the LPG therapeutic Massager for its effect on cellulite, a specific methodology based on physiological and pathological data was designed:

- **Global methodology** involving torso massage designed to improve circulation at the pelvic and abdominal level
- **Tissue mobilization** with specific maneuvers acting upon the venous system, lymphatic system, blood system which are sensitive to surrounding tissue movements
- **Adjusted suction power** to the sensitivity and the thickness of the tissues
- An average of **fourteen sessions** (two sessions per week) without interruption, during **35** to **45** minutes each.

Because this methodology represents a specific and innovative way to tackle this skin condition, the company decided to invent a name for it: the word "**Endermologie**" was chosen and became a trademark.

Thus, it was evident that Endermologie could be only done with the LPG Therapeutic Massagers because of the specificity of the patented heads.

To date the LPG devices such as therapeutic massagers have got the exempted claims:
Relieves minor muscles aches and pain
Temporarily increases local blood circulation
Relaxes muscles spasm
Since, April 1998, the LPG therapeutic massager has been permitted the claim:
Temporary reduction in the appearance of cellulite.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2000

Mr. Frederic Barthe
Vice President
LPG USA, Inc.
3101 North Federal Highway
Suite 301
Fort Lauderdale, Florida 33306

Re: K990445
Trade Name: LPG Therapeutic Massager Vibrator
Regulatory Class: I
Product Code: ISA
Dated: October 18, 1999
Received: October 20, 1999

Dear Mr. Barthe:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

6.2

510(k) Number K990445
Device Name: LPG Therapeutic Massager/Vibrator

Intended uses

- Relieves minor muscles aches and pains
- Relieve muscle spasm
- Temporarily improves local blood circulation
- Relieves minor muscle aches and pains, relieves pains, relieves muscle spasm and improves local circulation during burn rehabilitation

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use X OR Over-the-Counter-Use
(Per 21 CFR 901.109

(Optional Format 1-2-96) _____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990445