DEC 13 2005

K053149

510 (k) Summary of Safety and Effectiveness for Incentive Spirometer *SPIRO-BALL*

1. Submitter's name: LEVENTON S.A.

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   Contact person: Mr. Joaquim Soriano (General Manager)

   Date: 12.09.05

2. Trade name: SPIRO-BALL

   Common names: Volumetric Incentive Spirometer, Volumetric Exerciser

   Classification name: Incentive Spirometer (per 21 CFR 868.5690)

3. Legally marketed device: DHD EMERALD PRODUCT (COACH 2)

   510 (K) number: K970596

4. Description:

   SPIRO-BALL is a Volumetric Incentive Spirometer. It is a non-sterile device, which operates by inspiration, that lifts the piston placed inside the chamber.

5. Intended use:

   The SPIRO-BALL is a product for use in respiratory therapy and for adult people. It is intended for a single patient use, and it can be used both in the medical center and out of it (homecare therapies).

6. Technological characteristics versus predicate device:

Both SPIRO-BALL and the legally marketed device have the same technological characteristics:

- Equivalent product configuration (a cylindrical chamber which contains the piston, the indicator element of the air flowrate and the inspiration tube).
- Same operation mechanism: the piston goes up when inspiring through the tube, giving a more accurate indication of the volume when the air flowrate indicator is placed at the work flow rate.

7. Non clinical tests:

Non-clinical tests have been performed in SPIRO-BALL to demonstrate our product complies the established specifications. These tests have been done on products in normal conditions of use, but also in products subjected to extreme conditions of use.

8. Clinical tests:

Clinical tests have not been performed in SPIRO-BALL.

9. Tests conclusions:

All the tests performed in SPIRO-BALL (bench tests and physical and biological assays) demonstrate this device operates correctly, is safe for the user and is effective according its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2005

Leventon, S.A.
C/O Mr. Stefan Preiss
Responsible Third Party Official
TÜV America, Incorporated
1775 Old Highway 8
New Brighton, Minnesota 55112

Re: K053149
Trade/Device Name: SPIRO-BALL
Regulation Number: 868.5690
Regulation Name: Incentive Spirometer
Regulatory Class: II
Product Code: BWF
Dated: November 28, 2005
Received: December 7, 2005

Dear Mr. Preiss:

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) 276-0120. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K053149

Device Name: SPIRO-BALL

Indications For Use:

The Spiro-Ball is a product for use in respiratory therapy and for adult people. It is intended for a single patient use, and it can be used both in the medical center and out of it (homecare therapies).

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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 Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K053149