DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2005

Mr. Noam Hadas
S.L.P., Inc.
18 Hazfira St.
Tel-Aviv, Israel 67779

Re: K030869
Trade/Device Name: BiteStrip
Regulation Number: 21 CFR 890.1375
Regulation Name: Diagnostic electromyograph
Regulatory Class: II
Product Code: KZM
Dated: February 17,2004
Received: February 23,2004

Dear Mr. Hadas

This letter corrects our substantially equivalent letter of May 14, 2004, regarding the classification of your device which was incorrectly identified as "unclassified."

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 (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); 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 continue 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) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 S. Lin, PhD

Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

## INDICATIONS FOR USE STATEMENT

**510(k) Number: K030869**

**Device Name:** BiteStrip

**Indications for Use:**

The BiteStrip is generally indicated for use by orofacial pain professionals or dentists, to aid in the evaluation and management of nocturnal masticatory muscles activity disorders, which may be related to the patient's bruxism, temporomandibular disorder (TMD) or other oral function disorders during sleep.

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

510(k) Number _____

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off) Susan Runner

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030869

MAY 1 4 2004

K030869

**510(K) SUMMARY**

# BiteStrip

**510(k) Number K030869**

**Applicant's Name:** S.L.P Ltd.
18 Hazfira Street
Tel-Aviv 67779, Israel
Tel: 972-3-537-1281
Fax: 972-3-537-1282

**Contact Person:** Tamar Shochat
S.L.P Ltd.
18 Hazfira Street
Tel-Aviv 67779, Israel
Tel: 972-3-537-1281
Fax: 972-3-537-1282

**Trade Name:**

BiteStrip

**Classification Name:**

Muscle Monitoring Device

**Classification:**

The FDA has classified Muscle Monitoring Device as class II devices (product code KZM, Regulation No. unknown) and they are reviewed by the Dental Panel.

**Predicate Device:**

- Model K6-I Diagnostic System (Myotronics-Noromed. Inc. USA) cleared under K992694
- SleepStrip® Influent Ltd., Israel cleared under K002135
- ELECTROENCEPHALOGRAPH, (Nihon-Kohden America), cleared under K874796

**Performance Standards:**

The BiteStrip complies with the following recognized standards:
EN 60601-1-1:90 + A1(93) + A11(93) + A12(93) + A2(95) + A13(96)
EN 60601-1-2: 1993, EN 55011:1998 + A1:1999 class B

**Intended Use:**

The BiteStrip is intended as an aid in the evaluation of excessive nocturnal jaw muscle activity. The device is generally indicated for use by orofacial pain professionals or dentists, to evaluate nocturnal masticatory muscle activity level, which may be related to the patient's bruxism, temporomandibular disorder (TMD) or other oral function disorders during sleep.

**Device Description:**

The BiteStrip is a disposable diagnostic device. The device is intended for use in monitoring masseter muscle contractions during sleep. It is generally indicated for use by physicians to aid in the evaluation of the presence and severity of bruxism, to determine the need for treatment, and for treatment follow-up. The BiteStrip is specifically indicated to obtain a quantitative measure of masseter muscle contractions during sleep, which correlates with bruxism severity derived from formal sleep lab studies. The BiteStrip is intended for adult users during an overnight sleep episode, i.e., 4-6 hours.

The BiteStrip display gives an indication of muscle contraction severity as a single number, from 0 to 3 (Where 0 is very low count, and 3 is high count) depending on the total number of masseter muscle contraction episodes that the patient performs for the duration of the test. This number is referred to as the Bscore. While both Bscore and traditional bruxism score are very similar, and have good correlation, the terms differ because the bruxism score is measured using sleep lab EMG and additional physiological measures (not only EMG signals), while the Bscore is obtained by EMG analysis alone.