510(k) Summary
Lorenz Biotech S.p.A
Aptiva™ v2.13U

1. SPONSOR

AUG 2 4 2007

Lorenz Biotech S.p.A.
Via Statale 12, 109/B/C
41036 Medolla
Italy

Contact Person: Mr. Riccardo Isani
Email address: Riccardo.isani@lorenzbiotech.it
Date Prepared: August 6, 2007

2. DEVICE NAME

Proprietary Name: Aptiva™ v2.13U

Common/Usual Name: Transcutaneous nerve stimulator (TENS)
Biofeedback device
Electromyography device (EMG)
Nerve conduction velocity measurement device

Classification Name: Transcutaneous nerve stimulator (TENS)
Biofeedback device
Electromyography device (EMG)
Nerve conduction velocity measurement device

3. PREDICATE DEVICES

Functionality	Predicate Device
TENS	• Apex Medical Digital TENS (K021755) • GEMS-HV TENS (K032994) • Bioscope SD TENS (K970249) • Promax TENS (K022405) • NeuroTrain III (K003433)
Electromyography (EMG)/Biofeedback	• EMG Retrainer Dual Channel (K972487) • MES-9000/EMG System (K013399) • Synergy System (K981405)
Nerve conduction velocity (ENG)	Brevio (K010269)

4. DEVICE DESCRIPTION

The Aptiva™ v2.13U consists of a console on a mobile floor stand, power cord, battery charger, patient remote control, cables, and Manuals (*User and Application*). The Aptiva™ v2.13U is provided in four functional models (*Ballet, Flamenco, Hip-Hop, and Jazz*). EMG features are provided in the Ballet and Hip Hop models. One version of the Ballet model (*Option Etoile*) includes electroneurography (ENG) functions and a printer. Aptiva™ v2.13U uses commercially available electrodes. Models designated "Light" versions do not include the full treatment databases.

5. INTENDED USE

The Aptiva™ is a multifunctional transcutaneous electrical nerve stimulator (TENS) equipped with a surface electromyography and electroneurography.

Aptiva™ is indicated for symptomatic relief and management of chronic pain, intractable pain and/or as an adjunctive treatment for the management of post-traumatic pain.

The dynamic surface electromyography and electroneurography system is used for biofeedback, relaxation training, and muscle re-education as well as monitoring and display of bioelectric signals produced by muscles, stimulate peripheral nerves, and monitor and display the electrical activity produced by nerves.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Aptiva™ v2.13U is substantially equivalent to specified predicate devices based on intended use, indications for use, operational characteristics, and fundamental technological characteristics. Detailed side-by-side comparisons of the Aptiva™ v2.13U with cited predicate devices were included in the premarket notification and associated amendments.

7. PERFORMANCE TESTING

Testing included in this premarket notification includes electrical safety, electromagnetic compatibility, and design verification and validation testing. No materials of the Aptiva™ v2.13U are in direct contact with treatment sites and therefore no biocompatibility testing was provided. Test results demonstrate that the Aptiva™ v2.13U fulfills the prospectively defined performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 24 2007

Lorenz Biotech S.P.A.
C/O Rosina Robinson, RN, MEd, RAC
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K061828
Trade Name: Aptiva™ v2.13
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZJ, HCC, IKN, JXE
Dated: August 6, 2007
Received: August 7, 2007

Dear Ms. Robinson:

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 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, M.S.
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): K061828

Device Name: Lorenz Biotech Aptiva™ v2.13U

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 K061828